UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	
	Chapter 11
PURDUE PHARMA L.P., *et al*.,	**Case No. 19-23649 (RDD)**
Debtor.[1]	**(Jointly Administered)**

FIFTH MONITOR REPORT

Comes now, Stephen C. Bullock, as duly contracted Monitor for Purdue Pharma L.P. to report to the Court as follows:

EXECUTIVE SUMMARY

This Fifth Monitor Report, and the undersigned's first since being appointed on February 18, 2021, will include an outline of actions taken to date to determine compliance with the terms and conditions of the Voluntary Injunction, areas of further inquiry and recommendations provided to Purdue Pharma L.P., and the company's response to those recommendations.

Based on what has been reviewed to date and subject to the recommendations contained herein, Purdue Pharma and the Initial Covered Sackler Persons appear to be making a good faith effort to comply with the terms and conditions of the Injunction.

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

INJUNCTION AND MONITOR

1. On November 6, 2019, the Bankruptcy Court approved a Preliminary Injunction order as part of this bankruptcy case. The Preliminary Injunction order included a Voluntary Injunction ("Injunction") pursuant to which Purdue Pharma L.P. on its behalf and on behalf of its direct and indirect subsidiaries and general partner (collectively, "Purdue Pharma" or "the Company") agreed, among other things, to retain a Monitor with the responsibility to report on compliance with the Injunction every 90 days. The Preliminary Injunction has been amended several times, but the Injunction has remained substantively the same since November 2019. A copy of the currently operative Preliminary Injunction order, entered by the Court on April 22, 2021, including the Injunction is attached as Appendix A.

2. On February 13, 2020, Thomas J. Vilsack and Purdue Pharma executed the Purdue Pharma Monitoring Agreement. Secretary Vilsack (the "prior Monitor") filed reports with the Court on May 20, 2020, August 18, 2020, November 16, 2020, and February 3, 2021.

3. On February 18, 2021, the undersigned and Purdue Pharma executed the second Purdue Pharma Monitoring Agreement.

4. On March 1, 2021, the Bankruptcy Court approved the appointment of the undersigned as Monitor.

5. After being appointed and signing the protective order, the undersigned was granted access to documents that had been provided by Purdue Pharma to the prior Monitor.

6. On March 1, 2021, orientation documents and records were sent from counsel to the Company to the undersigned, and on March 2, 2021, an orientation meeting was held by videoconference. That videoconference included: Purdue Pharma's Executive Vice

President, General Counsel and Corporate Secretary; Associate General Counsel; Vice President, Business Operations; Vice President, Ethics and Compliance; and lawyers representing the Company from the Dechert, LLP law firm.

7. On March 9, 2021, the undersigned had a telephone conference with the prior Monitor.

8. On March 12 and 17, 2021, the undersigned participated in video conferences with representatives of the Unsecured Creditor Committee, Non-Consenting States Group, and the Ad Hoc Committee of Governmental and Other Contingent Litigation Claimants.

9. In addition to the orientation materials and access to the documents provided to the prior Monitor, the undersigned made information and document requests of the Company on March 2, 15, 29; April 12; and May 4, 2021. Materials were provided by Purdue Pharma to the undersigned on March 3, 8, 22, 25; April 8, 9, 13, 14, 15, 19, 21; and May 4, 5, and 10, 2021. Additional information was provided, and requests made, throughout the week in advance of filing this Report.

10. The materials provided by Purdue Pharma number in the thousands of pages and include both materials used by the Company in its business activities and operations, as well as materials generated just for the undersigned. Officials at Purdue Pharma have been generally responsive and cooperative in fulfilling these requests.

11. Interviews were conducted with the Director of Ethics and Compliance and the Associate Director of Ethics and Compliance. Brief individual videoconferences were also conducted with Purdue Pharma's Board Chair, President and CEO, and Chief Financial Officer. The Company has been responsive in arranging these interviews and has offered to facilitate other interviews.

12. The undersigned has continued contractual relationships with Jodi Avergun, who was assisting the prior Monitor relating to issues concerning Suspicious Order Monitoring, and Drake University School of Law, which has been providing assistance with document organization and paralegal tasks.

13. Prior to the filing of this report, the undersigned conducted outreach to lawyers at Milbank LLP and Debevoise & Plimpton LLP who serve as legal representatives of the Sackler family members and interests who are the Initial Covered Sackler Persons as defined and discussed in Sections I.K and II.I of the Injunction. The undersigned requested and received certifications of compliance with the terms and conditions of the Injunction applicable to the Initial Covered Sackler Family Persons.

DISCUSSION AND ANALYSIS

14. As will be discussed throughout, the Injunction has eight principal topic areas: Ban on Promotion; No Financial Reward or Discipline Based on Volume of Opioid Sales; Ban on Funding/Grants to Third Parties to Promote Opioids; Lobbying Restrictions; Ban on High Dose Opioids; Ban on Prescription Savings Programs; Self-Monitoring and Reporting of Direct and Downstream Customers; and measures specific to the Initial Covered Sackler Persons.

15. In addition to expressly setting forth what Purdue Pharma is prohibited from doing, the Injunction also describes activities that are not prohibited. Further, the Injunction sets forth the Appointment and Responsibilities of the Monitor and includes a definition section that covers many, but not all, of the terms used in the Injunction.

16. What follows is a review and assessment of Purdue Pharma's business organization, practices, and activities as they relate to some, but not all, facets of the

Injunction. For those facets of the Injunction and business practices that are not mentioned in this Report, their exclusion does not necessarily mean that the undersigned has concluded that there is compliance or noncompliance with those terms of the Injunction. Rather, it only indicates they have not been reviewed in depth for this Fifth Report.

17. The Report is organized by areas covered by the Injunction. Subheadings do not necessarily correspond to specific provisions in the Injunction and are instead used to assist in understanding the business activity, practice, or subject discussed. Those paragraphs containing recommendations and the Company's response are highlighted in bold. Those paragraphs identified as areas intended for further inquiry or review in the next report are italicized.

I. BAN ON PROMOTION AND FINANCIAL REWARDS BASED ON VOLUME OF OPIOID SALES

A. The Injunction

18. Section II.A of the Injunction sets forth the ban on promoting opioids or opioid products. "Promoting" is expressly defined in the Injunction as "the dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, does, and/or strengths of Opioid Products." (Injunction, I.O).

19. The prohibition Purdue Pharma agreed to covers activities relating to sales representatives, outside speakers, medical education programs, websites and social media, written publications, digital and printed advertisements, Internet search optimization techniques, and Internet marketing. (Injunction, II.A.1.a-h).

20. It also sets forth permitted activities that are not considered promotional activities, including maintaining websites; responding to unsolicited healthcare providers',

patients' and caregivers' requests for information relating to opioid products; providing information to payors, formulary committees and distributors concerning the opioid products; providing information in connection with the treatment of pain for end-of-life and cancer-related pain care; and various other permitted activities. (Injunction, II.A.2.a-k). In all events, however, Purdue's conduct permitted by the Injunction must be conducted in a manner that is consistent with CDC Guideline Recommendations, as applicable, and truthful not misleading, accurate and not deceptive. (Injunction, II.A.6.a-b).

21. In addition to a ban on promoting opioids, Purdue Pharma agreed to bans against promoting products that are indicated for the treatment of Opioid-induced side effects, if those activities could be construed as promoting opioids. The Injunction expressly prohibits sales representatives from these activities, as well as direct or indirect support for advertising these products. The Injunction also sets forth activities Purdue Pharma is allowed to do and expressly permits the promotion of products related to the treatment of opioid use disorders, abuse addiction or overdose, and rescue medications. (Injunction, II.A.3-4).

22. The Injunction also prohibits Purdue Pharma from either directly or through third parties engaging in promoting the treatment of pain or the concept that pain is undertreated in a manner that encourages use of opioids or opioid products. (Injunction, II.A.5.a-c).

23. The Company also agreed not to reward or discipline employees or third parties based on sales, prescribing use, or distribution of the opioid products. Specifically, Purdue Pharma agreed not to provide any financial incentive to its sales and marketing employees or take any disciplinary action against any of its sales and marketing employees directly based on or tied to the sales volume or quotas for opioid products. (Injunction, II.B.1).

24. Purdue Pharma also agreed not to offer to pay any remuneration directly or through a third party to any person or entity for the prescribing, sale, use, or distribution of opioid products. The Injunction expressly provides that it "shall not prohibit the provision of rebates or chargebacks." (Injunction, II.B.2).

B. Websites and Social Media Accounts

25. The undersigned reviewed the following websites and found all to be compliant with the terms of the Injunction: PurduePharma.com, ImbriumThera.com, AdlonTherapeutics.com, AvrioHealth.com, GreenFieldBioVentures.com, RhodesPharma.com, RxPatrol.com, SlowMag.com, ColaceCapsules.com, Senokot.com, Betadine.com, Butrans.com, HysinglaER.com, Oxycontin.com, AdhansiaXR.com, and AskPurdueMedical.com.

26. The undersigned reviewed the following social media websites and accounts and found all to be compliant with the terms of the Injunction: www.instagram.com/colacecapsules, www.instagram.com/betadine_us/, www.instagram.com/senokotus/, www.instagram.com/slowmagmg_usa/, Senokot YouTube - www.youtube.com/channel/UCgQT4lpRrJcKu5YyUp1FnqQ, Colace YouTube - www.youtube.com/channel/UCJ0kwpAlv4h-YECOF4MP9LQ, Slowmag YouTube - www.youtube.com/channel/UCDyAgCOnw7di_lUjNxKSDSA, Betadine YouTube - www.youtube.com/channel/UCVd-7CE3c1rDcGGEo8CBhwA, Adlon Therapeutics YouTube - www.youtube.com/channel/UCA7ASydGWjP-iSVAnrGwtFQ, twitter.com/purduepharma, twitter.com/ImbriumThera, twitter.com/AdlonThera, www.linkedin.com/company/purdue-pharma, www.linkedin.com/company/imbrium-

therapeutics, www.linkedin.com/company/adlon-therapeutics, and www.linkedin.com/company/greenfield-bio-ventures/.

27. The undersigned also reviewed the following websites of Purdue Pharma's customers and found that those sites did not include anything contrary to the terms of the Injunction: McKesson Corp., AmerisourceBergen, Cardinal Health System, CuraScript Specialty Distribution, Morris and Dickerson, JM Smith and Smith Drug Company, NACDS, and Express Scripts.

C. Marketing Budget and Market Share of Purdue Pharma Opioid Products

28. Of the entire sales and marketing budget for Purdue Pharma for 2020, approximately seven percent was spent on branded opioid products. Of that percentage, nearly 91% was spent on acquisition of data. The costs for data are equally spread across the branded opioid products.

29. The balance of the sales and marketing budget for the branded opioid products was for website maintenance, storage of data, postage, data transition and savings card expense. None of these investments appears to be used to promote opioid product sales.

30. Overall, the marketing budget for branded opioid products has been decreasing, spending 13% less in 2020 on opioid products for sales and marketing than the 2019 expenditures.

31. Prior to the Bankruptcy proceeding, based on Drug Enforcement Agency (DEA) records OxyContin had a market share of approximately 4% of prescription opioid product sales in the United States while today its market share in the United States has declined to approximately 1.1% for calendar year 2020, and accounted for 12.3% of the market of extended-release opioids.

32. According to financial records covering calendar year 2020 provided by Purdue Pharma, sales of OxyContin declined by approximately 13% from sales in 2019. Sales in 2019 declined by approximately 66% from sales in 2015.

33. According to financial records covering calendar year 2020 provided by Purdue Pharma, sales of Butrans declined by approximately 12% from sales in 2019 and by nearly 70% from sales in 2015. Butrans has declined to approximately 0.1% of all opioid sales for calendar year 2020 and accounts for 0.9% of the market of extended-release opioids.

34. According to financial records covering calendar year 2020 provided by Purdue Pharma, sales of Hysingla increased by approximately 3% from sales in 2019. Sales of Hysingla in 2020 decline by approximately 31% from high sales in 2017. Hysingla has declined to approximately 0.1% of all opioid sales for calendar year 2020 and accounts for 0.9% of the market of extended-release opioids ("ERO").

35. For Rhodes Pharmaceuticals, the branded and unbranded products represented 9.8% of the overall opioid market in 2020: MS-Contin (0.003% and 0.03% ERO)); Dilaudid (0.003%)); Rhodes Hydrocodone APAP (0.5%); Rhodes Hydromorphone (0.5%); Rhodes Oxycodone IR (1.5%); Rhodes Oxycodone APAP (5.4%); Rhodes Morphine ER (1.9% and 22.2 OF ERO).

36. Accordingly, Purdue Pharma products are 11.1% of the overall share of opiates sold in 2020 and 36.33% of the market for extended-release opioids.

37. Purdue Pharma's total net sales of opioids declined approximately 12% in 2020 compared to 2019 sales and is approximately 65% lower than total net sales in 2015.

38. The declines in marketing and sales expenditures, as well as the declines in sales and market share of opioid products, while not dispositive, are indicative that Purdue Pharma is complying with the terms of the Injunction relating to a ban on promotion.

D. Medical Information Team

39. One avenue by which Purdue Pharma has direct contact with not only customers, but also pharmacies, healthcare providers (HCPs), and the end-consumer of the opioid products is through Medical Services Inquiries. Purdue Pharma maintains a toll-free number and an email address by which anyone can call or write with questions about the products or the Company. Inquiries are also received in writing and through filling out web-based forms.

40. For the branded opioid products, the Medical Information team is responsible for responding to these requests. The team is comprised of employees of the Company and has both lay persons and a team of medical professionals who assist in responding to medical inquiries. It is run by a Director of Medical Information who reports to the Vice President of Medical Affairs. The Medical Affairs Department reports up to Purdue Pharma's Chief Scientific Officer. For products sold by Rhodes Pharmaceuticals, responding to medical inquiries is currently outsourced to an outside company. As of July 21, 2021, however, medical inquiries relating to Rhodes' products will also be responded to by Purdue's Medical Information team.

41. Each inquiry or request is logged with a case number and date and information including a description of the type of caller (class of contact), the geographic location, the product, the topic, and the question being asked. The logs also contain the response given to the inquiry. There were on average over 200 inquiries for the first three months of 2021 to

the Medical Information team, and over a hundred each month to the company responding to inquires made of Rhodes.

42. Inquiries come from HCPs, pharmacists, distributors, consumers, and others. The topics covered include many of the matters covered by the Injunction, from HCPs requesting sales visits and marketing materials, to consumers requesting patient assistance, discount coupons or referrals to HCPs, to requests that the Company provide or locate speakers to present on pain management.

43. Purdue Pharma has a document containing frequently asked questions (FAQs) to guide the responses of the Medical Information team, though the breadth of the subjects of inquiry extends beyond that which is covered by the FAQs documentation.

44. After reviewing the material capturing the inquiries and responses, the undersigned Monitor finds the responses and activities of Purdue's Medical Information team and Rhodes Pharmaceutical's vendor in compliance with the Injunction provision banning promotion of opioid products, as well as the provisions of the Injunction discussed in subsequent sections below.

E. Commercial Team and Pricing Arrangements

45. During the period from December 2019 to October 2020 Purdue Pharma had two third-party contract sales forces consisting of approximately 90 people for the purpose of promoting its non-opioid product, Adhansia XR®, which is authorized under the terms and conditions of the Injunction. An additional contract sales team for Adhansia was added in November 2020, with 60 additional customer service representatives. All three sales forces have received enhanced Adhansia training regarding how to address questions unrelated to the product.

46. At the recommendation of the prior Monitor, the sales force must certify that it understands and is complying with the Injunction, and that any inquiries about opioids or opioid products will be referred to Purdue Pharma's Medical Affairs Department.

47. Since the entry of the Injunction, no inquiries have been referred by the outside sales force to the Medical Affairs Department.

48. The Commercial Department has a number of employees who work, non-exclusively, on opioid-related matters which includes the Forecasting and Analytics team which develops sales forecasts; the Marketing Operations team which handles contracts for patient savings programs and updates to websites; the Customer Service team which handles product orders; the Pricing and Contracting team which handles product pricing, government price reporting, and certain types of agreements; and the Trade and Distribution team and Market Access team, discussed below.

49. During the period from December 2019 to the present, Purdue Pharma has had in-house and field-based Trade and Distribution and Market Access teams that work with wholesale customers and Pharmacy Benefit Managers (PBM), Managed Care Organizations (MCO), and Group Purchasing Organizations (GPO) to ensure formulary coverage and adequate supplies of branded opioid products are available.

50. For branded opioid products, the Trade and Distribution teams negotiate agreements with most of Purdue Pharma's wholesalers to distribute opioid products. Approximately 97% of the branded opioid products are sold to and distributed by McKesson, Cardinal Health, and AmerisourceBergen, an increase from 96% in 2019.

51. Purdue Pharma pays quarterly negotiated fees to its distributors per established agreements, paid quarterly as a credit against the purchase of branded opioid products. They are as follows:

a. a credit for maintaining a certain level of inventory;

b. a credit for maintaining a certain level of service quality;

c. a credit for limiting excess inventory;

d. a credit for an administrative fee for distributing product through a centralized location;

e. a credit for chargebacks, which is the difference between the price a wholesaler/distributor pays to Purdue Pharma and the price the Purdue Pharma's end contract customer pays to the wholesaler/distributor, which can be lower; and

f. a credit for providing data on inventory levels and sales to end customers.

52. In addition to these credits earned and given, Purdue Pharma also purchases general commercial prescription data and trade market access data from its wholesalers and third-party vendors that is allocated as an expense against branded opioid products. The data purchased includes national sales and inventory data from a variety of sources which is used by Purdue Pharma to track and/or forecast products and markets, plan production/manufacturing, assess distributor performance, and to document formulary performance.

53. Purdue Pharma also provides prompt payment discounts to its distributors.

54. While the specifics of the contracts have changed with the individual distributor-customers, the overall pricing and credit frameworks have not changed since the Injunction was entered in September 2019.

55. The Market Access team at Purdue Pharma focuses its efforts, in part, on overseeing the effort with MCOs and PBMs. Negotiations with managed care organizations and pharmacy benefit managers center on the formulary status of the products being sold. The benefit of being on a preferred status level in a formulary is that the co-pay paid by the ultimate customer is less than it would be if the drug were in a non-preferred status. Purdue Pharma pays a rebate to maintain the appropriate status.

56. For PBMs, MCOs and GPOs, the credits and payments negotiated to maintain formulary status or retain exclusivity for the use of Purdue Pharma opioid products within the various plans offered by these entities are as follows:

a. rebates;

b. price protection payments to restrict the impact of price increases that occur from time to time; and

c. administrative fees.

57. While the specifics of the contracts have changed with the individual entities, the overall pricing and credit frameworks have not changed since the Injunction was entered in September 2019, with exception of two PBMs that have negotiated a rebate for covered formulary lives, with no ancillary services provided. Purdue Pharma has explained that the two PBMs are requesting these new rebates from all of their customers and are not specific to Purdue Pharma or opioid products.

58. With federal and state programs, rebates and discounts are fixed by law, by regulation or by negotiated agreement.

59. For the products sold by Rhodes Pharmaceuticals, Purdue Pharma maintains a list of the some but not all of the current fee percentages paid to wholesalers, distributors, and

GPOs by Rhodes. The list reflects a variety of percentages for fees that reflect the complexity of arrangements Rhodes has with its customers, and the differences that arise between arrangements with customers for generic products and the limited number of branded products sold by Rhodes. Different fees are also assessed based on whether customers:

a. not only purchase product but also distribute product;

b. pass through the costs of bookkeeping, invoicing and billing;

c. have special arrangements with their own larger retail customer, or operate as if they are a group purchasing organization;

d. serve hospitals that purchase product by the unit as opposed to a bottle or box; and

e. have a certain volume of purchases.

60. Purdue Pharma retained a third party which conducted two studies in late 2019 to assess if the credits and fees it was paying were within the norm for the industry. One study was related to wholesaler/distributors, and one was related to PBMs and MCOs.

61. Regarding the wholesaler/distributors, Purdue Pharma commissioned a valuation analysis to establish a fair market value range of services paid to wholesalers for a variety of services provided to Purdue Pharma by the wholesalers. The third-party vendor performing the analysis used several different methods to calculate an acceptable range for the fees as a percentage of the Wholesale Acquisition Cost (WAC), which is the list price for each branded opioid product available to all authorized classes of the trade that purchase directly from Purdue Pharma. The survey found the fair market range of the fees to be between 3.47% to 9.9% of the WAC.

62. A similar survey was concluded by the same vendor for the fees and credits paid to PBMs and MCOs. The ranges established by the study depended in part on the extent of data provided by the PBM or MCO, but the fair market range for base data arrangements was 2.29% to 5.28% of the WAC, while the range for more enhanced data arrangements was 2.75% to 6.3% of the WAC.

63. Most, but not all, of the fees paid by Purdue Pharma are within the range determined by the aforementioned analyses and surveys. A principal reason that some fee percentages appear high is that the fees relate to generic product sold by Rhodes Pharmaceuticals which are established, without negotiation, as a "take or leave" condition of doing business with the Rhodes customer.

64. In addition to the Company's review, the prior Monitor also conducted a review of the system of rebates, service fees, price protection payments, and other financial remunerations used by Purdue Pharma. Upon request and with Court approval, the prior Monitor retained the services of HealthData Solutions Inc. (HDS) located in Ohio. HDS provides analysis for hospitals about the reasonableness and fairness of rebates and other remunerations being made available to their clients.

65. HDS was charged with reviewing the system of rebates, service fees, price protections, and other financial remunerations used by Purdue Pharma with wholesaler, group purchasing organizations, managed care operations, and governmental entities (Second Report, Paragraph 31). The review was designed to determine whether or not payments, credits and discounts provided by Purdue Pharma were reasonable or unreasonable and consistent or inconsistent with normal business practices and industry ranges for similar payments, credits, and discounts.

66. HDS requested and received information covering the time period from January 2018 to mid 2020 involving Purdue Pharma's arrangements with wholesaler-distributors, PBMs, MCOs, and State Medicaid Departments. HDS concluded following its review that "there was not a positive relationship between the fees paid per unit and the total units sold," and "there was no statistical evidence that Purdue Pharma is incentivizing sales volumes through increasing average fees paid per unit."

67. Throughout his tenure, the previous Monitor noted that the varied and proprietary nature of payments, credits, and discounts make it difficult to determine if any payment, credit, discount or data purchase is outside a normal range that might suggest non-compliance with the Injunction.

68. While the undersigned Monitor has not yet interviewed Purdue Pharma's Commercial team, based on information reviewed to date, the undersigned agrees with the prior Monitor's sentiment.

69. There are at least two different provisions of the Injunction that should be considered regarding arrangements Purdue Pharma has made related to the pricing and sales of its opioid products: the prohibition against promoting opioid products (Injunction, II.A), and the prohibition against offering any remuneration directly or through a third party to any person in return for the sale, use or distribution of opioid products (Injunction, II.B.2).

70. The Injunction agreement expressly permits the use of rebates and/or chargebacks, though the terms "renumeration," "person," "rebates" and "chargebacks" were not defined in the Injunction.

71. Neither the Company's survey nor the HDS review directly resolve whether the pricing and rebate provisions are consistent with the terms of the Injunction.

72. Regarding Purdue Pharma's surveys, the determination of the market value of the pricing discounts and fees for the respective customers does not necessarily ensure that there is compliance with the Injunction. The Purdue Pharma studies do not indicate whether the market values are consistent with industry norms, or in any way financially compensate the wholesalers, PBMs, and GPOs in a manner inconsistent with the terms of the Injunction.

73. The limitations of the HDS review include:

a. First, HDS only reviewed information from Purdue Pharma relating to the branded opioid products from 2018 until the third quarter of 2020 in concluding that Purdue Pharma's practices didn't incentivize sales volume. Just because the pricing practices have remained consistent over the period of time does not necessarily lead to the conclusion that those practices – in place even prior to the Bankruptcy and Injunction – don't incentivize sales volume. The review did not include an assessment of the pricing practices relating to the opioid products compared to non-scheduled drugs, or any consideration of whether the pricing practices of Purdue Pharma are consistent with industry norms and standards of other manufacturers selling controlled substances.

b. Second, the undersigned is not aware that there was any meaningful analysis of the practices in the generic market.

74. **Accordingly, the undersigned recommends that during the next 90 days, an additional review be undertaken regarding the Company's pricing practices, comparing among other things any differences in practices between scheduled and nonscheduled products, and the pricing practices of scheduled drugs across the industry. Once identified, the Monitor will request court approval of a third-party**

consultant to assist in undertaking this review. The Company agrees to this recommendation.

F. Purdue Pharma's Manufacturing and Procurement Quotas

75. Pursuant to the Federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and implementing regulations, the Drug Enforcement Agency (DEA) sets aggregate manufacturing and production quotas for certain controlled substances, including opiates. Upon application, the DEA then allocates individual manufacturing and procurement quotas to manufacturers. The DEA can revise a company's quota at any time during the year as a result of increased or decreased sales or exports, new manufacturers entering the market, new product development, or product recalls.

76. The undersigned Monitor examined information detailing DEA established procurement and manufacturing quotas granted to Rhodes Technologies and Purdue Pharmaceuticals for products to either sell or convert, and manufacturing quotas granted to Purdue Pharma L.P. for finished dosage forms of opioids and opioid products for sale covering the years 2018 to 2021, and projections for 2022.

77. In most instances, the DEA has not fully granted to Rhodes Technologies or Purdue Pharma the requests the Company has made. The granted requests for quota to commercialize oxycodone, hydrocodone, and morphine all decreased from 2020 to 2019.

78. However, the requests granted for quota for Active Product Ingredient ("API") used in the manufacture of finished doses of oxycodone for sale in 2021 to date already exceed the total that was granted in 2020. The same holds true for hydrocodone between 2021 and 2020. In both instances, the Company's justification in internal documents is "to support Product Development (Project Catalyst)".

79. The question raised by this data is whether an increase in quota, both requested by the Company and granted by the DEA, is intended to support an increase in the amount of opioid products sold.

80. It is the undersigned's understanding that Project Catalyst refers to the divesture of substantially all of the assets of Rhodes Technologies, including the manufacturing facility in Coventry, Rhode Island that manufactures API, the active ingredient which is contained in medicine. The Coventry facility has been manufacturing API for Purdue Pharmaceuticals and Rhodes Pharmaceuticals.

81. In September of 2020 an agreement was finalized to sell the manufacturing facility and substantially all of assets of Rhodes Technologies to Noramco. The transaction closed on December 31, 2020.

82. The Company has explained that, as part of this divestiture, Purdue Pharmaceuticals entered into a long-term agreement with Noramco to provide to Purdue Pharmaceuticals the API necessary to continue to manufacture Purdue Pharma's and Rhodes Pharmaceuticals' products, including their opioid products. As a consequence of Project Catalyst, some of the production of API that historically was made at the manufacturing site owned and operated by Rhodes Technologies could be transitioned to different sites under this third-party supply agreement.

83. As part of that process, it became necessary for Purdue Pharmaceuticals to manufacture test batches of finished product to ensure that quality and safety standards are met. Separate quota requests were made of and granted by the DEA to support these test batches, not to produce an increased amount of opioid products for sale. To that end, the Company has explained to the undersigned Monitor that not only will the test batches not

enter the stream of commerce, but the Company must account to the DEA later this year as to the destruction of the test batches of finished product.

84. However, even if one disregards or subtracts the quota requested and received relating to Project Catalyst and only considers the commercial request, the requests granted for quota for API used in the manufacture of finished doses of oxycodone hydrocodone for sale in 2021 substantially exceed that which was granted in 2020.

85. *Over the upcoming months the undersigned will seek additional information from Purdue Pharma, both as relates to the increased quota attributable to Project Catalyst and the disposition of the test product, and as to the increased quota from 2020 to 2021 more generally.*

G. Bonus, Salaries and Incentives to Purdue Employees

86. In 2019 bonus and financial incentives for Purdue Pharma and its related entities were based on a company scorecard identifying three factors to be used to determine if a bonus should be paid out: Value Creation (30%), Innovation and Efficiency (60%), and People and Culture (10%).

87. Following entry of the Injunction, the 2020 the scorecard criteria were significantly changed. The basic three factors – or strategic pillars – of Value Creation, Innovation and Efficiency, and People and Culture remained the same. Purdue Pharma's branded business operating profit remained a factor of the Innovation and Efficiency pillar, but the Company provided that it would reward behavior that promoted an entrepreneurial mindset and advanced sales of only non-opioid products. As a result, the 2020 approach no longer rewarded staff based on volume of opioid sales or profit generated from the sale in part of opioids and opioid products.

88. For the 2021 scorecard, the weighting of the strategic pillars was changed to Value Creation (40%), Innovation and Efficiency (50%), and People and Culture (10%). While Purdue Pharma's operating profit continues to be a factor in the corporate scorecard, the scorecard provides that the "[a]ctual performance will be adjusted for the margin on branded opioid sales being higher or lower than Target," making express that the Company has decoupled the performance of the opioid products from corporate objectives and benchmarks.

89. Opioid products are included, however, in the strategic pillar relating to Value Creation. Specifically, the 2021 Scorecard provides that 1.8% of the overall bonus and incentive target relates to "Delivery of Project Catalyst Implementation Plan to include regulatory submission of the following API transfers: Oxycodone APAP Tabs [oxycodone/acetaminophen] and Oxycodone Tabs."

90. The Injunction requires that Purdue Pharma "shall not offer or pay any remuneration . . . to or from any person in return for the prescribing, sale use or distribution of Opioid Product." (II.B.1). If new, different or transferred opioid products are approved, by tying the compensation to the regulatory submissions, it is the Monitor's belief that these employees will have been rewarded for the "sale, prescribing or use of the opioid products." However, if remuneration simply reflects that Purdue facilitated regulatory approval to procure API from a different facility, which seems more likely as set forth above, rewarding employees for this successful transfer would presumably be consistent with the Injunction.

91. *Over the upcoming months the undersigned will seek additional information from Purdue Pharma relating to Project Catalyst and the regulatory submissions to make the determination whether including this as a part of the bonus and incentive structure is consistent with the Injunction.*

92. For the six field-based employees of the Market Access Team who handle sales to managed care organizations and group purchasing operations, in 2020 Purdue Pharma used a slightly different system to provide salaries, bonuses, and incentives. There were two factors involved in the process in the Market Access Incentive Compensation Plan used to determine the qualifications for bonuses or incentives for that six-member team: performance and corporate performance. The prior Monitor concluded that neither factor involved the top line for opioid sales value or volume as a factor in fixing salaries or awarding bonuses or incentives. (Fourth Report, Paragraph 9).

93. The undersigned received but has not fully analyzed the 2021 and bonus and incentive compensation structure for the Market Access Team. The Company reports that its structure and core components are the same as was in place for 2020. *The undersigned will include a review of that system in the next report.*

II. BAN ON FUNDING/GRANTS TO THIRD PARTIES TO PROMOTE OPIOIDS

A. The Injunction

94. Under Section II.C.1- 6 of the Injunction, Purdue Pharma agreed not to provide any financial or in-kind support to any third party, medical society, or patient advocacy group for the purpose of promoting opioid or opioid products. This prohibition included, among other things, providing links to third-party websites related to opioids or opioid products; knowingly using a third party, including HCPs, to engage in an activity prohibited by the

Injunction; enabling or advocating for the appointment of a director, board member, employee, agent, or officer to serve in a similar capacity concurrently in any entity that promotes opioids, opioid products or opioid related treatment of pain or opioid related side effects.

95. The Injunction expressly states it doesn't prohibit any of these activities with entities principally involved in the treatment of opioid use disorders, the prevention, education and treatment of opioid abuse, addiction or overdose, and rescue medications. (Injunction, II. C.7).

B. Grants and In-Kind Contributions

96. Grants and in-kind contributions are decided by virtue of a multi-disciplinary committee that includes personnel from the Law department and Ethics and Compliance department. Personnel from the Commercial Department of Purdue Pharma are not involved in making decisions involving the awarding of any grants or in-kind contributions, and Purdue Pharma prohibits making any contribution requested by any customer.

97. In 2020 up through early May 2021, Purdue Pharma awarded grants and contributions totaling $3,848,429. Eighty-three percent of the total grants went to universities, nonprofits, health care providers, and other organizations addressing prevention, harm reduction, treatment and recovery of opioid misuse or abuse. Eleven percent of the grants were identified as relating to COVID-19, and the remaining six percent of the grants were for areas such as wellness, education and economic development.

C. Spend Reports and Research Payments

98. Payments made to HCPs must be reviewed under the terms of the prohibitions above, as well as the prohibitions against paying any remuneration in return for the prescribing, sale use or distribution of opioid products, discussed in the previous section.

99. The prior Monitor reviewed state audit reports from California, Connecticut, Nevada, Vermont, and Massachusetts and the Federal Spend Reports for Purdue Pharma for 2018, as well as the records for the first two months of 2019, and concluded that there were no payments that would have violated the Injunction had it been in place in 2018.

100. The undersigned has reviewed the federal spend report for 2020. While there are some payments relating to opioids, it is a very small number relative to the overall spend. However, any expenditure, even small, must be consistent with the agreed-upon Injunction.

101. Regarding research payments, the prior Monitor noted that, although the material he had reviewed was in draft format, "[i]nformation on the website and documents provided by Purdue Pharma indicate that the only opioid related research that was funded in 2019 by Purdue Pharma relates either to the current 11 post marketing FDA required efforts that predated the Injunction or research related to a product called nalmefene which is a hydrochloride injection medication being tested to counteract an opioid overdose." (First Report, paragraph 64).

102. The undersigned Monitor requested from Purdue Pharma all research payments in 2019, 2020 and 2021, the status of the opioid-related research referenced in the Monitor's First Report, as well as any new opioid-related research involving the Company. That material was recently provided but has not yet been fully analyzed.

103. *Prior to the next report, the undersigned will review updated state audit reports, and information concerning research and research payments to third parties, to both better understand the projects and payments made and to ensure compliance with the Injunction.*

III. LOBBYING RESTRICTIONS

A. The Injunction

104. Purdue Pharma agreed to certain restrictions related to lobbying and advocacy, including not to directly or through a third party advocate for federal, state, or local legislation or regulations that: encourages or requires a HCP to use opioids, or sanctions the HCP for the failure to prescribe or use opioids for the treatment of pain; limits access to non-opioid alternative pain treatments; or pertains to the classification of any opioid product as a scheduled drug under the Controlled Substances Act. (Injunction, II.D.1).

105. Purdue Pharma further agreed that it wouldn't advocate against certain measures including the use non-pharmacological or non-opioid pharmacologic therapy for the treatment of pain, the use of immediate release opioids instead of extended release opioids, the use of lowest possible dosages limits on an initial prescription of an opioid product, reasonable preconditions including testing before prescribing an opioid product, the use of evidence-based treatments for opioid use disorder, the implementation of proper disposal system, or limits on the operation or use of Prescription Drug Monitoring Programs (PDMPs). (Injunction, II.D.2-3).

106. In addition to Purdue Pharma's internal government affairs department, the Company contracts with 22 different advocacy businesses at the state level and three entities following federal legislation.

107. The prior Monitor made a number of recommendations relating to lobbying and advocacy, which were accepted by the Company. Those recommendations included:

a. That the agreements with the state and federal consultants be in writing and spell out the terms of the injunction and that those lobbyists both provide quarterly reports of the issues they are engaged in and certifications that they are abiding by the terms of the Injunction.

b. That the Company refrain from lobbying against the passage of an opioid tax, absent written notice to the Monitor.

c. That any employee serving on the board of any organization that engages in lobbying or educating state and federal officials must recuse them themselves from discussion or decisions on policies the impact of which would be to more easily enable or promote the use of opioid products, and must refrain from participating in any work group that focusses on promotion of products or issues not otherwise permitted by the injunction.

d. That Purdue Pharma provide the Monitor a quarterly report of all political contributions that related to an agreement reached between all interested parties and the court relating to certain political contributions.

e. That any Purdue Pharma employee serving on the board of an organization that engages in lobbying or educating state and federal officials on policies that could promote the use of opioids or opioid products must recuse from any board discussions relating to opioids, and refrain from participating in any working groups that focus on issues prohibited by the Injunction. (Second Report, para. 90).

108. The undersigned Monitor has reviewed 25 quarterly reports for the first quarter of 2021 reflecting lobbying at the state and federal level and finds that Purdue Pharma is in compliance with Part II, Section D of the Injunction.

109. The Company provided the undersigned a description of the political contributions made by Purdue Pharma in 2021, and finds they are in compliance with the agreement reached by the parties and the Court.

110. *The undersigned Monitor has not yet received from Purdue Pharma updated information concerning the boards and organizations to which Purdue employees belong, and will update for the next report, upon receipt of the information from the Company and review of the relevant organizations.*

IV. BAN ON HIGH DOSE OPIOIDS

111. Under Section II.E of the Injunction, Purdue Pharma agreed to abide by whatever decision is made by the Food and Drug Administration (FDA) on the pending Citizens Petition dated September 1, 2017 concerning a ban on high doses of prescription and transmucosal opioids exceeding 90 morphine milligram equivalents (FDA-2017-P-5396).

112. A review of Regulations.gov finds that no action has been taken by the FDA on this Citizens Petition.

V. BAN ON PRESCRIPTION SAVINGS PROGRAM

A. The Injunction

113. Under Section II. F. of the Injunction, Purdue Pharma agreed it would not directly or through a third party promote savings cards, vouchers, coupons, or rebate programs to HCPs for any opioid product, or provide financial support to a third party to circumvent this restriction. However, Purdue Pharma is authorized to provide savings cards,

vouchers, coupons or rebate programs, including point-of-dispense programs, in response to requests from HCPs, patients or caregivers, or on its company and product-specific websites.

B. Purdue Pharma's Savings Programs

114. As noted by the prior Monitor and confirmed by the undersigned, a review of company records indicated that Purdue Pharma discontinued a savings card for Butrans opioid products because a generic less expensive product became available.

115. However, through a third-party vendor Purdue Pharma still offers a savings card for OxyContin and Hysingla products, and a point-of-dispense savings program for OxyContin, Hysingla and Butrans subject to certain terms and conditions.

116. The savings card for OxyContin can be used once every 12 days with a prescription and is limited to 13 redemptions per 12-consective month period. After the patient pays the first $45, the savings card allows up to $70 of savings on each prescription. It is available only for commercially insured patients.

117. The savings card for Hysingla can be used once every seven days with a prescription and is limited to 18 redemptions each year, but only 15 at the same dose. After the patient pays the first $25, the savings card allows up to $170 of savings on each prescription. It, too, is available only for commercially insured customers.

118. For both OxyContin and Hysingla, there are conditions and restrictions that are communicated on the company websites. The savings card information available for both products includes the "boxed warning" required for the products by the FDA. The savings card information available for both products through the company website makes reference to the package insert, medication guide, and prescribing information for the products that sets

forth a variety of warnings concerning the products and limitations on when and for what conditions the products should be used.

119. In addition to the company websites, inquiries about the savings cards are often fielded by Purdue's Medical Information team. A review of the responses made by that team are consistent with the terms of the Injunction, as the responses direct the patient to the website or the phone number on those websites.

120. Purdue Pharma also offers electronic vouchers for OxyContin, Hysingla and Butrans. The electronic vouchers can be considered a point-of-dispense program, as the benefit is received at in-network pharmacies without the patient taking any action or even necessarily having knowledge of the program.

121. The electronic voucher for OxyContin is up to $70 savings on each prescription, with a minimum patient copay of $20. The patient must first meet an initial co-pay threshold of at least $25 and less than $250. It is available only for commercially insured patients and cash patients are not eligible. It is limited to 26 redemptions in a 365-day period.

122. The electronic voucher for Butrans is up to $85 savings on each prescription that has at least four transdermal systems, after the patient pays the first $15. It is available only for commercially insured patients and cash patients are not eligible. It can be applied for every 21 days and is limited to 22 redemptions per year, with only 16 at the same dosage strength.

123. The electronic voucher for Hysingla is up to $270 savings per prescription for the first three months of the year, after the patient pays the first $15. From April through December, the savings is reduced to $170 on each prescription. It is available only for

commercially insured patients and cash patients are not eligible. It can be applied for every 21 days and is limited to 18 redemptions per year, with only 15 for the same dosage strength.

124. There are no references to the electronic voucher programs on any of the company websites. Nor was any information found as a result of general internet searches.

125. There have been no substantive changes to the existence or terms and conditions of the savings card and electronic voucher programs since the Injunction was entered.

126. The offering and execution of these plans under the current terms and conditions outlined appear to be in compliance with the Injunction.

C. Savings Programs Not Directed by the Company

127. A basic internet search that includes the names of Purdue Pharma's branded opioid products brings up any number of websites purportedly offering coupons and comparing prices for these products.

128. *Over the next 90 days and prior to the filing of the next report, the undersigned will take measures to better understand these websites and their connection, if any, to the Company.*

VI. SUSPICIOUS ORDER MONITORING AND REPORTING

A. The Injunction and Federal Law and Guidance

129. Under Section II.G.1.a-c of the Injunction, Purdue Pharma agreed to operate an effective monitoring and reporting system to detect suspicious orders and possible diversion of opioids and opioid products by direct customers and to identify whether downstream customers pose a material risk of diversion. In doing so, Purdue Pharma agreed to reasonably analyze all collected direct customer date and utilize available downstream customer data, and information that Purdue Pharma receives.

130. Purdue Pharma must also, upon a state's request, report to relevant state agencies any direct or downstream customers identified as part of the Suspicious Order Monitoring, and any customer relationship in each state that was terminated because of an unreasonable risk of diversion or unreasonable risk of potential for diversion. (Injunction, II.G.1.d).

131. The Injunction also requires that, upon request, Purdue Pharma promptly provide reasonable assistance to law enforcement agencies involved in investigations of potential diversions or suspicious circumstances involving Purdue Pharma opioid products. (Injunction, II.G.2).

132. The Injunction further requires that if one or more of the three largest pharmaceutical distributors establishes a system to aggregate transaction data involving the sale of opioid products and/or reports of suspicious orders, Purdue Pharma would provide information into that system to the extent available and feasible, provided the system is designed to use information provided by manufacturers of opioid products. (Injunction, II.G.3).

133. Finally, Purdue Pharma agreed to refrain from acting as a distributor of opioid products (aside from rescue and treatment medications) directly to a retail pharmacy or health care provider that would require it to be registered as a distributor under the Controlled Substances Act unless otherwise required by local, state, or federal law. (Injunction, II.G.4).

134. In addition to the Injunction, federal law requires that Purdue Pharma and other manufacturers of opioid products design and operate a system to disclose suspicious orders of controlled substances and to inform the Field Division Office of the DEA in its area when a suspicious order is discovered. A suspicious order is defined as "an order of unusual size,

orders deviating substantially from a normal pattern, or orders of unusual frequency." (21 CFR §1301.74(b)). Although the Federal government requires companies like Purdue Pharma to establish a suspicious order monitoring and reporting system, it does not endorse or approve any system or approach to implement compliance.

135. Since the Injunction was entered and the prior Monitor filed his first report, Purdue Pharma has made improvements and enhancements to its Suspicious Order Monitoring (SOM) and Suspicious Order Reporting (SOR) practices, including increasing staffing, enhancing initial review of new customers, reporting all orders of interest to the Drug Enforcement Administration, automating procedures, creating a more structured review of potentially suspicious orders, and capturing the processes and procedures in updated Standard Operating Procedures.

B. Staffing

136. Initially, the Company charged the Ethics and Compliance Department with operating the SOM program and directed the Associate Director of Ethics and Compliance to lead that effort, with backup assistance provided by three additional Purdue Pharma employees.

137. The Associate Director of Ethics and Compliance ("AD") has been in this role since March 2019. From 2012 to 2018, she was an Associate Director of the Law Enforcement Liaison and Education program within Purdue Pharma's Corporate Security Department.

138. The AD is a veteran law enforcement officer having served 15 years in the state of Georgia. Her last post prior to working for Purdue Pharma was as the Principal Agent for

the Georgia State Medical Board. She also served as the Georgia Chapter President of the National Association of Drug Diversion Investigators (2003-2020).

139. One of the recommendations of the prior Monitor was that Purdue Pharma increase staffing in the Ethics and Compliance so that additional resources could be devoted to the SOM program. Consistent with the recommendations of the prior Monitor, Purdue Pharma added two additional employees to the SOM team in a fulltime capacity, and one in part time or backup capacity:

a. Purdue Pharma created and filled the role of Director of Ethics and Compliance in September 2020. The Director, a long-time Purdue Pharma employee, now manages the SOM program. For most of the past decade, he has been either the Director of Controlled Substance Compliance or the Director of Corporate Security at Purdue Pharma and had provided part-time assistance with the SOM program. Prior to joining Purdue Pharma, the Director spent thirty years with the Drug Enforcement Administration, last serving as Special Agent in Charge of the New York Field Division.

b. Purdue Pharma also created and filled the role of Manager of Ethics and Compliance in January of 2021. The Manager is responsible for assisting with reviewing, summarizing, tracking, analyzing and conducting investigative research relating to SOM. The Manager of Ethics and Compliance had previously worked as an Auditor for the New York City Department of Investigations, as a Special Investigator in the New York City Health and Hospitals Office of the Inspector General, and as a New York City law enforcement officer.

c. Finally, the employee responsible for security and diversion control operations at Purdue Pharma's manufacturing facility in Wilson, North Carolina is also providing assistance with the SOM program, on an as-needed or fill-in basis.

140. Prior to the staff additions, the overwhelming majority of the responsibilities for the suspicious order monitoring and reporting rested with one individual, the Associate Director of Ethics and Compliance.

141. **Over the next 90 days, the undersigned recommends working with the Company to assess the efficiencies, necessary and needed redundancies, and impact of additional staffing on the SOM program to better ascertain whether additional staffing might be recommended. The Company agrees to this recommendation.**

142. What follows is a summary of the system in place, the information and data gathered that informs that system, some of the changes made to that system since the Injunction was entered, as well as recommendations for further improvement.

C. Onboarding of Customers: Initial Due Diligence and Annual Review

143. The term "customer" can be confusing, as it is nowhere defined in the Standard Operating Procedures (SOMs) or the Injunction. Purdue Pharma and Rhodes only sell to wholesale distributors; so, in total, Purdue Pharma only had 15 direct-purchase customers in 2020 while Rhodes had 59. And, of those customers, 97% of Purdue Pharma's sales and 96% of Rhodes' sales in 2020 occurred through three distributors.

144. The seeming low number under-represents the complexity of the distribution and sales process, however. In practice, most individual distributor-customers have many distribution facilities across the nation, each of which is a separately registered DEA distribution facility.

145. Moreover, Purdue Pharma interacts not just with the distributors, but also a variety of entities including group purchasing operations, pharmacy benefit managers, hospitals, and managed care organizations in negotiating rebates, discounts , payments and fees for Purdue Pharma products. Although not in a price setting context, Purdue Pharma and Rhodes also interact with health care providers, pharmacies, and the end-user customer through inquiries made to the Medical Affairs Department, as previously discussed.

146. There are also a limited number of entities that undergo the initial and ongoing due diligence review that are not distributors of the Company's opioid products, including pharmacies, pharmacies in hospitals, and healthcare providers. These rare instances are principally, if not exclusively, accounts where Purdue is donating buprenorphine/naloxone tablets, indicated for opioid dependence. The undersigned finds these activities to be consistent with the terms of the Injunction, as it expressly provides that Purdue Pharma isn't prohibited from acting as a distributor of medications relating the treatment of opioid abuse, addition or overdose, including medication-assisted treatment for opioid addiction and rescue medications for opioid overdose. (Injunction, II.G.4).

147. Purdue requires that all customers it ships controlled substances to, regardless of type, complete the due diligence form, annual review, and have a site visit.

148. For the purposes of the discussion of the SOM program, however, the discussion is limited to the role in the distribution process played and is largely limited to the direct customer of the company, which is the wholesale/distributor, and the downstream pharmacy customer, which is serviced by the wholesaler/distributor.

149. Before a distributor can order controlled substances from Purdue Pharma, the Company's SOPs require that the distributor must complete a due diligence questionnaire, a

wholesaler annual review form, as well as have a member of the Ethics and Compliance Department conduct a physical or virtual site visit. Moreover, each year the customer must submit an updated due diligence and annual review form. These updated forms are received by Purdue Pharma from June through August.

150. According to the Standard Operating Procedure CC-SOP-18 v.4, revised in December 2020, the due diligence questionnaire is a 22-question survey that includes gathering information relating to: the states in which the distributor ships products; type of SOM and reporting system in place; onboarding, monitoring and evaluating customers; processes the distributor takes in identifying and reporting suspicious orders to the DEA (including whether thresholds are established and adjusted); interactions with the DEA or state regulatory agencies; training of staff regarding prevention of drug diversion; and information concerning the types of customers the distributor has — and the interaction with those customers — concerning the SOM processes.

151. Additionally, the wholesaler annual review requires wholesalers to provide information concerning changes in ownership; disciplinary actions from the DEA; the number and type of customers (retail independent pharmacies, hospitals, retail chain pharmacies, closed door pharmacies, mail order pharmacies, physician offices, wholesalers, government/DOD, veterinary offices, pain clinics, other); and the point of contact for SOM annual paperwork, pended orders, questions re chargeback data and downstream customer review.

152. Among other purposes, Purdue Pharma uses information provided by the customer on the annual review form to establish the thresholds for each distributor, discussed below.

D. Site Visits

153. In addition to the due diligence questionnaire and the annual review, prior to ordering opioid products from Purdue Pharma, the SOP requires that a member of Purdue Pharma's Ethics and Compliance Department conducts a virtual site to assess the effectiveness of the customer's SOM program, corroborate details provided about that program, assess the physical security controls in place, and discuss the Purdue Pharma SOM program with the wholesaler.

154. Additionally, Purdue Pharma's Standard Operating Procedure CC-SOP-000018 v.4 requires that a physical site visit of each wholesaler occur at least one time to corroborate the information obtained from the Due Diligence Questionnaire, or "as needed to address SOM compliance concerns or substantial changes in the customer's business model or SOM program."

155. The AD of Ethics and Compliance conducted 20 site visits in 2020, and five site visits in 2021 as of April 13, 2021. All but four in early 2020 have been virtual site visits, consistent with DEA guidelines implemented due to COVID-19. In response to written inquires, Purdue Pharma has explained that all the site visits since January 2020 have been conducted "due to new customer SOM compliance."

156. While, in the past, the AD escalated site visit reports to the Vice President of Ethics and Compliance if issues were identified, going forward the new Director of Ethics and Compliance will review every site visit report and further escalate as necessary.

157. Of the site visit reports reviewed by the undersigned, the visits center around the company, the professional experience of key employees and total employees, the customer's SOM processes, the company's relationship and contact with law enforcement, and the

physical layout of the customer's facility. In each instance recommendations are made regarding training in topics of drug diversion and supply chain networking and resources. In some instances, specific recommendations are made, such as the importance of conducting downstream customer site visits.

158. Based on the Ethics and Compliance Department's review of the customer's initial due diligence questionnaire responses, the annual review, and the site visits, Purdue Pharma decides whether it will release opioid products to that customer. According to CC-SOP-18, Purdue Pharma prohibits a distributor/customer from ordering if the distributor fails to provide its SOP or summary of SOM program; if the SOM program is deficient in meeting the requirements required by the DEA; fails to provide number of customers to which it distributes/services/repackages controlled substances; or if the review of the customer concludes there is an unreasonable risk of diversion.

159. The prior Monitor had found that a number Purdue Pharma's customers provided questionnaire responses that were incomplete, unsigned, unresponsive, or lacked accompanying documentation.

160. *Prior to the next report, the Monitor will review the due diligence questionnaire responses and annual reviews received by the Company in 2021 and will report the findings.*

161. Additionally, of the 25 site visits in 2020 and 2021, Purdue Pharma states that one site visit resulted in the decision not to do business with the customer. However, based on the Monitor's review, Purdue Pharma's SOM pended and then reported a suspicious order to DEA over two weeks after that customer site visit occurred. Moreover, in another instance, a customer that repackages for both manufacturers and distributors filled out its initial due diligence and annual review on October 15, 2020, and the site visit was conducted

almost one month later, on November 11, 2020. However, the customer had placed an order in October, and based on the October Chargeback report, was an outlier meriting further review.

162. The prior Monitor noted in his Final report that the schedule of inspection visits had been accelerated, and the Company has stated that site visits are now covered on a rotating basis. It is not clear to the undersigned that inspections have been accelerated or whether there are any inspections separate and apart from the initial onboarding of customers.

163. **While recognizing that COVID-19 impacted many intentions, the Monitor recommends that the Company establish guidelines for assessing under what circumstances and how often it conducts site visits to current customers and consider whether in person site visits should be conducted after a certain amount of time has elapsed from the last in person inspection. The Company agrees to this recommendation.**

164. **The Monitor further recommends that no orders can be taken from new customers until the site visit is complete and determined to be acceptable under the criteria set forth above. The Company agrees to this recommendation.**

E. Suspicious Order Monitoring Review

165. According to the Standard Operating Procedures (CC-SOP-17 v.3 and CC-SOP-21 v.1), every single order of controlled substances processed by customer service of Purdue Pharma and Rhodes undergoes a review prior to fulfilling. The purpose of that review is to identify orders of unusual size, frequency or that substantially deviate from a normal pattern.

166. To do so, Purdue Pharma employs a cloud-based IT program, developed by a third-party vendor, that uses both an algorithm and a proprietary "threshold" to identify any orders meriting further review. Those orders meriting further review are then deemed an "order of interest," and are held for further review prior to being fulfilled. The algorithm was developed by the vendor, and the Company calculates thresholds for each customer.

1. Algorithm

167. According to CC-SOP-21 and information provided from the third-party IT vendor to the Monitor, the algorithm is developed by analyzing 24 months of sales data for each customer. The algorithm evaluates the customer's past purchases, as well as the new orders, by both the product's National Drug Code (NDC) and the Active Ingredient Group (AIG).

168. The algorithm also evaluates the current order compared to that customer's previous largest order by AIG, past individual orders, and the historical average of that customer's monthly orders. It also compares the amount of active ingredient ordered relative to all other customers, as well as all other customers in the same class of service.

169. As earlier noted, three customers purchase 97% and 96% of the branded and generic opiate products, respectively. However, those customers have multiple distribution centers. Those individual distribution centers have unique DEA registration numbers and service downstream customers unique to that individual distribution center. Accordingly, each of the customer's distribution centers are deemed individual customers in the SOM system.

170. If there is no history of the customer or customer's distribution center ordering that product in the last 12 months, the SOM system will immediately pend the order, requiring Ethics and Compliance to make a determination whether to reject or clear the order.

2. Customer Thresholds

171. In addition to the algorithm review, the order is also assessed to determine whether it exceeds that customer's threshold.

172. At its most basic level, a customer's threshold is defined for purposes of the SOM process as the "[m]onthly maximum quantity in dosage units for each DEA controlled substance base code and/or strength unique to a customer."

173. Calculating a customer's threshold is a laborious manual process that takes the AD many months each year to complete. As described by the AD, a customer's threshold is calculated by taking the aggregate sales of Purdue and Rhodes products for each product ingredient and comparing that to the national dispensing data representing sales for each product ingredient. This establishes a baseline, and that baseline number is multiplied by a store count provided by each customer. The store count is derived from information obtained from the customer's due diligence questionnaire and the annual review questionnaire, broken down by the type of enterprise (retail, long term care etc.). The final step in the process is to multiply that customer-specific number by a fraction, based on the status of each customer.

174. The status of the customer is established by the Company's commercial team and reflects whether the customer is a preferred customer (ordering that product or drug family from the Company the majority of the time), secondary (ordering from the Company because of a supply chain issue or other reason requiring a secondary supply), or a default customer (an established customer with no specific status).

175. Thresholds are adjusted annually based on National Prescription Audit (NPA) data and the customer information provided on the annual review questionnaire. Over 1,000 thresholds are manually calculated each year by the Associate Director of Ethics and Compliance.

176. Once the thresholds for each customer and each product are established, Purdue Pharma provides those thresholds to the SOM IT vendor which inserts those thresholds as additional "rules" against which orders are evaluated. If a customer order exceeds a particular threshold established by Purdue Pharma, the automated system will pend the order for review. Accordingly, the cloud-based system will now pend orders that either are identified as outliers by the algorithm or that exceed the product and customer specific thresholds set by Purdue Pharma personnel.

177. Thresholds can be adjusted if a customer alerts Ethics and Compliance of increases or decreases in the number of customers served at any time. At least since January 2020, however, there have not been any midyear adjustments to the annual thresholds of Purdue Pharma's customers

178. The factors for determining the customer thresholds have remained consistent since the prior Monitor was initially appointed. However, there is an effort underway to embed mathematical calculations into the spreadsheets, thereby reducing some of the manual calculations.

179. Regarding the thresholds, over the past year, the prior Monitor raised several questions or concerns about the threshold, including:

a. Each Threshold is primarily established by a single employee who calculates the Threshold manually on annual basis.

b. To date, the threshold review process has been manual – meaning an individual employee has created the threshold for each customer, and, when an order is pended as an order of interest, compared that order to the threshold that the employee had created.

c. The use of the Threshold in this fashion had the effect of overriding the algorithm based IT cloud base system that is actually designed to identify orders that meet the legal criteria of a suspicious order and of the DEA guidance purportedly relied upon in establishing the SOM system at Purdue Pharma.

180. In October 2020, Purdue Pharma contracted with its vendor that operates its SOM cloud-based program to upgrade and enhance its SOM practices. Among other recommendations, the vendor suggested that the threshold analysis should supplement the algorithm model, the thresholds must be kept current, and there should be multiple eyes on the threshold development and evaluation.

181. **Consistent with the vendor's recommendations, the Monitor recommends that, now that the Ethics and Compliance team responsible for SOM has been augmented, a review by an additional staff member of each of the threshold calculations, occur. The Company agrees to this recommendation.**

182. **Further, to the extent that the factors in calculating the thresholds are changed by automating or embedding some of the calculations into the spreadsheets, the Monitor recommends that the Company provide advance notice to allow the Monitor to review and comment on the proposed changes prior to its implementation. The Company agrees to this recommendation.**

F. Process for Evaluation of Pended Orders/Orders of Interest

183. CC-SOP-17 establishes the process that occurs once an order is pended by the system. Specifically, once an order of interest is identified by the cloud-based system, Ethics and Compliance staff undertake an evaluation of that order, which may include: (a) reviewing the order details; (b) reviewing the customer's order history, including the 12-month average of purchases; (c) reviewing the specific active ingredient and NDC's associated with order; (d) reviewing the customer threshold; (e) checking journal entries in the SOM system for information related to the order; (f) reviewing any pertinent customer correspondence; and (g) inquiring with Purdue Pharma's customer service team, or directly with the customer as needed.

184. For each of the pended orders, Ethics and Compliance conducts an evaluation of that order and completes a SOM Order Review Checklist. The checklist captures whether the order was within limits of the algorithm or if it pended on the algorithm based on unusual size, frequency or pattern, or for other reasons; and whether it exceeded or was within the customer's threshold. The evaluation then captures whether the customer was contacted and any response provided, the decision whether to release or reject the order; and any comments of the reviewer.

185. The review and intervention triggered by an order being pended from the time of the entry of the Injunction had been conducted primarily by the Assistant Director of Ethics and Compliance at Purdue Pharma. She has also been responsible for the site visits, calculating the thresholds, and a review of chargebacks, to be discussed below. Since September 2020, the responsibilities of reviewing orders of interest have now been

distributed so that the Director and the Assistant Director share the responsibility for reviewing these pended orders.

186. In January through March of 2021, 3,359 orders were processed through the SOM cloud-based IT system, with 488 of those orders automatically pended by the system. This represents 14.5% of all orders, an increase from last year's 13%. All of those pended orders were reported to the DEA per the practice put in place by the Company at the recommendation of the prior Monitor in October 2020. After an additional review, as discussed below, all but 13 of those orders were filled. Those rejected orders separately were reported to the DEA.

1. Review of Pended Order Justifications for February and March 2021

187. The SOM system reviews customer orders at the line-item level. For illustration, in February of this year, out of 5,672 order lines, 942 lines or approximately 16.6% of the orders made were pended; one order was rejected. In March 2021, out of 6,147 order lines, 808 lines or approximately 13% of the orders made were pended; one order was rejected.

188. The cloud-based system provides the capability of providing summary reports that not only capture the lines cleared and pended, but also a summary of the review undertaken by Ethics and Compliance.

a. In reviewing the summary reports for February and March 2021, the vast majority of the orders of interest in those months were pended because of either a lack of sufficient history for the customer, which automatically pends the order requiring further intervention, or a change in the frequency of an order. In both instances, this occurred because of a change in where the wholesaler wanted the products shipped due to weather disruptions.

b. Some of the orders pended because it was a new customer to Purdue Pharma; some because the customer had reached a new award status; some pended because they were infrequent customers for that specific product or the customer was ordering a new strength of the drug family; some because other companies were backordered or other supply chain issues, so they were turning to Rhodes products.

c. In some instances, Ethics and Compliance reached out directly to the customer to explain why an increase in size or frequency of orders occurred, or to discuss the increased ordering based upon the customer's forecasts.

d. The one rejected order in February was, according to the distributor, a reflection of one large pharmacy chain's order from the prior week. In March, the rejected order was because a downstream customer had initially ordered more of a product than was needed and requested to cancel the order. Rather than cancelling, however, the Company's practice is to reject the order and send that information to DEA.

189. The prior Monitor noted that, "A review of the SOM reports and of the explanation given for clearing hundreds of orders flagged by the cloud-based IT system and the algorithm reveals that nearly 90% of the orders are noted to have cleared because of threshold review only." (Second Report, Paragraph 68.) While the threshold and limits are still often one of the bases for clearing orders of interest, the SOM reports now capture additional analysis and it is evident to the undersigned Monitor that the overwhelming majority of the orders are no longer cleared based on the threshold review, alone.

190. In his final report, the prior Monitor wrote:

> Improvements have been instituted including better documentation of orders flagged as pended orders or orders of interest. Within that system Purdue Pharma officials make requests for additional information to determine if orders should be shipped or if diversion is taking place downstream. In almost every case of follow

> up Purdue Pharma officials accept the representations of officials from their customers. To further strengthen that system of follow up I would recommend that monthly Purdue Pharma select a number of follow up cases in which Purdue Pharma would require additional back up information from the customer. This request should be defined to provide additional information and documentation of the basis and explanation of why a particular order should not be considered a suspicious order. (Fourth Report, para. 15).

191. To date, the undersigned is not aware that any customers have been selected or a process has been established for seeking additional backup information.

192. The undersigned has some reservations that the above-recommendation suggests that Purdue Pharma can rely on its customers' statements without verifying them, but only occasionally needs to actually take the step of verification. In reviewing the February and March 2021 SOM Reports, it is clear that, of the over 1,700 pended orders, there are fewer than ten different bases upon which the customer justified the reason the order of interest was of unusual size, frequency or deviating from the normal pattern.

193. **During the next 90 days the undersigned recommends working with the Company to ensure that the underlying concern expressed in the prior Monitor's above-recommendation is addressed and explore whether there is a better way to capture or ensure some degree of corroboration of the customer's representations, if the representation is an observable fact. The Company agrees to this recommendation.**

G. Chargebacks and Review of Downstream Customers

194. In addition to Suspicious Order Monitoring and Reporting related to its direct customers, the Injunction requires Purdue Pharma to review and monitor downstream customers who are purchasing product from a Purdue Pharma customer and distributing it to their downstream customers. The purpose of the system is to identify downstream customers

of interest who may be ordering and dispensing quantities that may be exceeding national or customer dispensing averages.

195. The system principally relies upon third-party data that details downstream customer purchases: chargeback reports, and "867" and "852" data.

196. At its most basic, chargebacks are the difference between the price a wholesaler/distributor pays to Purdue Pharma and the price the wholesaler sells to Purdue Pharma's end-contract customer, which can be lower as a result of negotiated contracts with Group Purchasing Organizations. The 867 data reflects the inventory of the distributor-customer and 852 data reflects inventory levels of downstream customers.

197. From the time of the injunction until August 2020, these reports were reviewed quarterly by the Associate Director of Ethics and Compliance – the same employee that has been tasked with creating thresholds and reviewing and investigating all pended orders. At the prior Monitor's suggestion, chargeback data is now reviewed monthly, and the newly-hired Manager of Ethics and Compliance will assume principal responsibility of reviewing this data.

198. A typical monthly chargeback report is a spreadsheet reflecting the number of units to be credited for each downstream customer. Ethics and Compliance takes an average of the chargeback data for downstream customers based upon their relative size and the type of customer or patient services that the downstream customer provides. Downstream customers that have a significantly larger number of chargeback units than other customers contained in the same report are then flagged as customers of interest, or "outliers," for further review.

199. For each outlier since September 2020, Ethics and Compliance has developed a standardized review that assesses fifteen different factors: (1) census information; (2) distance to nearby hospitals, cancer centers, and VA centers; (3) distance to nearby pharmacies; (4) distance to physician offices, specialties, data waived physicians; and Opioid Treatment Programs; (5) pharmacy board license verification and disciplinary history; (6) pharmacist in charge license verification and disciplinary history; (7) general internet search and customer comments; (8) Google earth photo of location; (9) social media information; (10) public/private database search (RX Patrol, NADDI, streetrx); (11) overdose statistics for local & state areas; (12) state pharmacy board review of most recent meeting minutes; (13) ARCOS DEA retail buyer statistics; (14) State PMP details if available; and (15) DEA Diversion sanctions/verification of registration. The reviewer also identifies whether Purdue Pharma's customer, the wholesaler/distributor, was contacted about its customer's order. These factors are outlined in CC-SOP-19.

200. While the Assistant Director of Ethics and Compliance explained during an interview that the activities listed in the above paragraph follow the processes that she had been undertaking prior to September 2020, the addition of the Outlier Report and SOP-19 formalizes that exercise and ensures a degree of standardization that isn't entirely dependent on the reviewer.

201. SOP-19 provides that, if the review doesn't dispel questions concerning the downstream customer, or if the distributor doesn't provide requested due diligence information, the Downstream Customer of Interest will be referred to the DEA and the distributor will be notified.

202. In January and February of 2021, alone, there were over 400,000 chargebacks each month.

203. Of those, 23 were identified as potential outliers in February, and six in January. In five instances the distributor was contacted, though there is nothing on the report indicating why these outliers merited contacting the distributor, while the others did not. Moreover, there is nothing in the Outlier Reports indicating or suggesting this information was provided to the DEA or any further action was taken. In one outlier review, the license of the pharmacist in charge was inactive, but no further action was taken. In 19 of the 29 reviews, the Outlier Reports noted that they will continue to monitor the downstream customer.

204. In the December 2020 Outlier Report, there were notations of continuing to monitor outliers that had first been identified as outliers two months prior.

205. To date, the method used for the chargeback review has been manual, and no IT cloud-based system, algorithm, or threshold is used in the review. As part of the Company's efforts over the past seven months and at the request of the Monitor, Purdue Pharma is in the process of implementing a new IT program that will aggregate and enhance the information gathered in order to more effectively and assess the actions of downstream customers. While it is not evident the proposed system identifies downstream orders of interest, it moves away from a spreadsheet review and may provide better information for the Ethics & Compliance Department to identify the outliers.

206. The potential for error in identifying orders of interest when over 400,000 lines of data is considerable and should not be dismissed. Moreover, even when an order of interest is identified and further reviewed, there is nothing in the SOP-19 or on the Outlier

Report that would indicate when a downstream customer should be reported to the DEA, or even when the downstream customer's distributor should be contacted. Accordingly, it is not apparent that the Downstream Customer review, as currently designed, is serving any meaningful value in identifying, halting or reporting suspicious orders.

207. *Over the next three months, the undersigned will evaluate and assess the updates to the Chargeback system and make recommendations to the Company, if warranted.*

H. Other Requirements under the Injunction and Prior Monitor's Recommendations Relating to Suspicious Order Monitoring and Reporting

208. From the entry of the Injunction to date, the Company has not been asked to provide support to law enforcement as is required by Section II.G.2 of the Injunction. A review of records of the Medical Information team found that it has responded to one call from law enforcement over the past year with questions about the packaging of one of Purdue Pharma's products, following the robbery of a pharmacy.

209. While Purdue Pharma does review the SOM plans for each of its wholesale customers, the Company is not aware of any of the distributors establishing a system to aggregate data concerning transactions of opioid products and reporting of suspicious orders. (Injunction, II.G.3). Review of the distributors' websites and general internet searches lead to the same conclusion.

210. The Injunction requires the Company to report to relevant state agencies any direct or downstream customers identified as part of the Suspicious Order Monitoring and customer relationships in each state terminated because of an unreasonable risk of diversion or potential for diversion. (Injunction, II.G.1.d). However, according to the Company, the state of West Virginia is the only state that has reporting requirements. Purdue has been providing information to the West Virginia Board of Pharmacy.

211. The prior Monitor requested the opportunity to review and approve each of the updated SOPs relating to Suspicious Order Monitoring. Subject to a minor change that has been discussed with Purdue Pharma, the undersigned approves of the updated SOPs. However, additional revisions may be necessary due to Purdue's efforts to automate the threshold and review processes, and to maintain consistency with the recommendations made herein.

VII. INITIAL COVERED SACKLER PERSONS

A. The Injunction

212. Section II.I. provides that members of the Sackler family identified in the Injunction ("Initial Covered Sackler Persons") agreed not to be actively engaged in the opioid business in the United States other than by virtue of their ownership interest in Purdue Pharma and that they would individually or collectively take no action interfere with the Purdue Pharma's responsibilities and duties under the Injunction.

213. Purdue Pharma's General Counsel stated to the undersigned Monitor that the only communication with any of those members of the Sackler family has been through their legal counsel, and there has been no action taken by the identified family members that would interfere with Purdue Pharma's responsibilities and duties under the Injunction.

214. A review of the boards, officers and management team of each entity reflects no Initial Covered Sackler Person serving in any such capacity.

215. The undersigned has received signed certifications from the Initial Covered Sackler Persons or their representatives certifying that they have not actively engaged in the opioid business in the United States and have taken no action to interfere with Purdue Pharma's compliance with the Injunction.

VIII. MISCELLANEOUS

216. After being appointed as Monitor, the undersigned became aware that Purdue Pharma had provided a grant of $50,000 in January 2010 to the Montana Attorney General's Office. Reflected in documents in the possession of the Company, the grant was provided in response to a request by the Prescription Drug Abuse Program Coordinator in the Montana Attorney General's Office, to support a prescription drug abuse and prevention awareness campaign.

217. The undersigned served as Montana Attorney General from January 2009 to January 2013. While the undersigned recalls the abuse and prevention awareness campaign and our efforts to enact a Prescription Drug Monitoring Program in Montana, the undersigned was unaware, or did not recall, that the Montana Attorney General's Office received a grant from Purdue Pharma. As a result, when initially seeking consideration to fill this position, the undersigned did not disclose the 2010 grant from Purdue Pharma to the Montana Attorney General's Office.

The Undersigned Monitor respectfully submits this Fifth Report with the recommendations contained herein.

STEPHEN C. BULLOCK
Monitor

APPENDIX A

Preliminary Injunction and Voluntary Injunction

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: **PURDUE PHARMA L.P., *et al.*,** **Debtors.**[1]	**Chapter 11** **Case No. 19-23649 (RDD)** **(Jointly Administered)**
PURDUE PHARMA L.P., *et al.*, **Plaintiffs**, **v.** **COMMONWEALTH OF MASSACHUSETTS, *et al.*,** **Defendants.**	**Adv. Pro. No. 19-08289**

SEVENTEENTH AMENDED ORDER PURSUANT TO 11 U.S.C. § 105(a) GRANTING MOTION FOR A PRELIMINARY INJUNCTION

Upon the motion, dated September 18, 2019 ("**September 18, 2019 Motion**"), of Purdue Pharma L.P. and certain affiliated debtors, as debtors and debtors in possession (collectively, "**Debtors**"), that are plaintiffs in this adversary proceeding, for an order pursuant to section 105(a) of title 11 of the United States Code ("**Bankruptcy Code**") and Rule 7065 of the Federal Rules of Bankruptcy Procedure ("**Bankruptcy Rules**"), to (i) enjoin the governmental defendants in this adversary proceeding ("**Governmental Defendants**") from the commencement or continuation of their active judicial, administrative, or other actions or

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

proceedings against the Debtors that were or could have been commenced before the commencement of the case ("**Governmental Actions**") that are included in the chart annexed hereto as Appendix II, as well as the commencement or continuation of any other actions against the Debtors alleging substantially similar facts or causes of action as those alleged in the Governmental Actions, and (ii) enjoin the Governmental Defendants and the private defendants ("**Private Defendants**") in this adversary proceeding from the commencement or continuation of their active judicial, administrative, or other actions or proceedings, included in the chart annexed hereto as Appendix III, and the commencement or continuation of other actions alleging substantially similar facts or causes of action as those alleged in the actions identified in Appendix II and Appendix III, against current or former (a) owners (including any trusts and their respective trustees and beneficiaries), (b) directors, (c) officers, (d) employees, and (e) other similar associated entities of the Debtors that were or could have been commenced before the commencement of the case ("**Related Parties**," as identified in Appendix III,[2] and the claims

[2] The Related Parties are: The Purdue Frederick Company Inc.; The P.F. Laboratories Inc.; Purdue Pharma Technologies Inc.; PLP Associates Holdings L.P.; PLP Associates Holdings Inc.; BR Holdings Associates L.P.; BR Holdings Associates Inc.; Rosebay Medical Company L.P.; Rosebay Medical Company, Inc.; Beacon Company; PRA Holdings Inc.; Pharmaceutical Research Associates Inc.; Purdue Holdings L.P.; Rhodes Pharmaceuticals Inc.; Rhodes Technologies Inc.; Coventry Technologies L.P.; MNP Consulting Limited; Richard S. Sackler; the Estate of Jonathan D. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; the Estate of Beverly Sackler; Beverly Sackler; Theresa Sackler; David A. Sackler; Marianna Sackler; Estate of Mortimer Sackler; Estate of Raymond Sackler; Trust for the Benefit of Members of the Raymond Sackler Family; Raymond Sackler Trust; Beverly Sackler, Richard S. Sackler, and Jonathan D. Sackler, as Trustees Under Trust Agreement Dated November 5, 1964; Beverly Sackler, Richard S. Sackler, and Jonathan D. Sackler, as Trustees Under Trust Agreement Dated November 5, 1974; Paulo Costa; Cecil Pickett; Ralph Snyderman; Judith Lewent; Craig Landau; Mark Timney; Stuart D. Baker; Frank Peter Boer; John Stewart; Russell Gasdia; Marv Kelly; Shelli Liston; Heather Weaver; Doug Powers; Lori Fuller; Rodney Davis; Brandon Worley; Donald Leathers; Wendy Kay; Michael Madden; LeAvis Sullivan; Jeffrey Ward; Beth Taylor; Leigh Varnadore; Paul Kitchin; Mark Waldrop; Mark Radcliffe; Mark Ross; Patty Carnes; Carol Debord; Jeff Waugh; Shane Cook; James David Haddox; Aida Maxsam; Tessa Rios; Amy K. Thompson; Joe Coggins; Lyndsie

against them described in this paragraph, the "**Related-Party Claims**"); and the Court having jurisdiction to decide the Motion and the relief requested therein under 28 U.S.C. §§ 157(a)-(b) and 1334(b); and there being due and sufficient notice of the Motion; and the Court having reviewed the Complaint, the September 18, 2019 Motion, the Debtors' brief in support of the September 18, 2019 Motion, the declarations in support of the September 18, 2019 Motion, and other evidence and argument submitted by the Debtors in support thereof; all pleadings filed in support of the September 18, 2019 Motion; and all objections filed in opposition or partial opposition to the September 18, 2019 Motion, as well as all filed letters in response to the September 18, 2019 Motion; and upon the record of and representations made at the hearing held by the Court on the September 18, 2019 Motion's request for entry of a preliminary injunction on October 11, 2019 (the "**October 11, 2019 Hearing**") and at the hearing held on November 6, 2019 (the "**November 6, 2019 Hearing**"); and, after due deliberation and for the reasons set forth on the record by the Court at the foregoing hearings, good and sufficient cause appearing, the Court having entered Orders on October 11, 2019 granting the Motion in part and on October 18, 2019 and November 6, 2019 amending such Order; and upon a motion dated March 4, 2020 by the Debtors to extend the Preliminary Injunction for 180 days, until October 5, 2020 (the "**March 4, 2020 Motion**"); and upon the record of and representations made at the hearing held by the Court on the March 4, 2020 Motion (the "**March 18, 2020 Hearing**"); and after due deliberation and for the reasons set forth on the record by the Court at the March 18, 2020 Hearing, good and sufficient cause appearing, the Court entered an order on March 30, 2020 granting the relief requested in the March 4, 2020 Motion; and upon a motion dated September

---

Fowler; Mitchell "Chip" Fisher; Rebecca Sterling; Vanessa Weatherspoon; Chris Hargrave; Brandon Hassenfuss; Joe Read; Andrew T. Stokes; Nathan C. Grace; Jaclyn P. Gatling; Leslie Roberson; Barbara C. Miller; Briann Parson-Barnes; Becca Beck Harville; Lindsey Bonifacio; Tammy Heyward; James Speed; Damon Storhoff; Diana C. Muller; and Draupadi Daley.

16, 2020 by the Debtors to extend the Preliminary Injunction for 147 days, until March 1, 2020 (the "**September 16, 2020 Motion**"); and upon the record of and representations made at the hearing held by the Court on the September 30, 2020 Motion (the "**September 30, 2020 Hearing**"); and after due deliberation and for the reasons set forth on the record by the Court at the September 30, 2020 Hearing, good and sufficient cause appearing, the Court entered an order on October 1, 2020 granting the relief requested in the September 16, 2020 Motion; and upon a motion dated February 14, 2021 by the Debtors to extend the Preliminary Injunction for 23 days, until March 24, 2021 (the "**February 14, 2021 Motion**"); and upon the record of and representations made at the hearing held by the Court on the February 14, 2021 Motion (the "**March 1, 2021 Hearing**"); and after due deliberation and for the reasons set forth on the record by the Court at the March 1, 2021 Hearing, good and sufficient cause appearing, the Court entered an order on March 1, 2021 granting the relief requested in the February 14, 2021 Motion; and upon a motion dated March 12, 2021 by the Debtors to extend the Preliminary Injunction for 28 days, until April 21, 2021 (the "**March 12, 2021 Motion**"); and upon the record of and representations made at the hearing held by the Court on the March 12, 2021 Motion (the "**March 24, 2021 Hearing**"); and after due deliberation and for the reasons set forth on the record by the Court at the March 24, 2021 Hearing, good and sufficient cause appearing, the Court entered an order on March 24, 2021 granting the relief requested in the March 12, 2021 Motion and overruling the objections of the Non-Consenting States [ECF No. 233], the Ad Hoc Committee on Accountability [ECF No. 232], and certain Tennessee Public Officials [ECF No. 231] to the March 12, 2021 Motion; and such Orders having contemplated a procedure to amend the Orders further; and the Court having entered Orders on November 20, 2019, December 9, 2019, January 2, 2020, February 17, 2020, March 4, 2020, April 14, 2020, May 18, 2020, July

20, 2020, August 31, 2020, October 1, 2020, and October 31, 2020 amending such Orders further and enjoining actions brought by Additional Plaintiffs; and upon the Court having reviewed the Debtors' timely motion to extend the Preliminary Injunction until and including May 20, 2021 filed on April 7, 2021 ("**April 7, 2021 Motion**," together with the September 18, 2019 Motion, March 4, 2020 Motion, September 16, 2020 Motion, the February 14, 2021 Motion, and the March 12, 2021 Motion, the "**Motions**"), the Debtors' memorandum of law in support of the April 7, 2021 Motion, all pleadings filed in support of the April 7, 2021 Motion, and the two objections filed in opposition or partial opposition to the April 7, 2021 Motion; and upon the record made at the telephonic hearing held by the Court on April 21, 2021 on the April 7, 2021 Motion ("**April 21, 2021 Hearing**," together with the October 11, 2019 Hearing, the November 6, 2019 Hearing, March 18, 2020 Hearing, September 30, 2020 Hearing, March 1, 2021 Hearing, and the March 24, 2021 Hearing, the "**Hearings**") and all of the proceedings herein; and after due deliberation and for the reasons stated by the Court at the April 21, 2021 Hearing, the Court having determined that the Debtors have established good and sufficient legal and factual grounds to amend and extend such orders as provided therein and grant the Debtors' request to amend and extend the orders as provided in this Amended Order, which amends and supersedes the prior orders. Now, therefore, the Court finds and concludes as follows:

(a) The Defendants in this adversary proceeding are the Governmental Defendants and the Private Defendants that, along with the Additional Plaintiffs, are listed in the "Underlying Plaintiffs" column of each of the charts annexed hereto as Appendix II and Appendix III, with such Appendices being made a part of and incorporated in this Order. The Defendants in this adversary proceeding and the Additional Plaintiffs are all plaintiffs in judicial, administrative, or other actions or

proceedings that seek to hold the Debtors and/or the Related Parties, as identified in Appendix III, liable in connection with claims and/or causes of action arising out of or otherwise related to the Debtors' prescription opioid business.

(b) The Court has jurisdiction over this adversary proceeding pursuant to 28 U.S.C. §§ 157(a)-(b) and 1334(b). This adversary proceeding is a core proceeding pursuant to 28 U.S.C. § 157(b)(2).[3]

(c) The Debtors have demonstrated that the continuation of the active litigation against them and the Related Parties, identified in Appendix II and Appendix III, respectively, would result in irreparable harm to the Debtors and their reorganization.

(d) The representatives of the Raymond Sackler family and of the Mortimer Sackler family (collectively, the "**Sackler Families**") agreed on the record at the October 11, 2019 Hearing to toll all applicable statutes of limitations and similar time limits on the commencement of Additional Actions against any member of the Sackler Families, and to treat as inoperative all deadlines (including deadlines for appeals) in any currently pending Related Party Claim against any member of the Sackler Families, for the duration of this preliminary injunction.

(e) Accordingly, this Court finds it appropriate to extend the preliminary injunction as provided herein pursuant to section 105(a) of the Bankruptcy Code and Rule 7065 of the Bankruptcy Rules.

(f) The legal and factual bases set forth in the Complaint, the Motions, other supporting papers, and at the Hearings establish just cause for the relief granted herein.

[3] The Court does not hereby make any determination that the Governmental Actions and Related-Party Claims are core proceedings.

(g) Arizona, California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Idaho, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Nevada, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin, the Ad Hoc Group of Non-Consenting States (as listed on the October 11, 2019 Verified Statement pursuant to Bankruptcy Rule 2019 filed under Docket No. 296 of Case No. 19-23649), the ad hoc committee of government and other contingent litigation claimants and each of its members (as listed on the October 10, 2019 Verified Statement pursuant to Bankruptcy Rule 2019 filed under Docket No. 279 of Case No. 19-23649), and the Multi-State Governmental Entities Group and each of its members[4] (as listed on the October 30, 2019 Verified Statement pursuant to Bankruptcy Rule 2019 filed under Docket No. 409 of Case No. 19-23649) (collectively, the "**Voluntarily Bound Parties**") have each consented and agreed to continue to abide by the terms of the *Seventeenth Amended Order Pursuant to 11 U.S.C. § 105(a) Granting Motion for a Preliminary Injunction*, without the need to have any order entered against them.

Based on these findings, it is hereby:

ORDERED, that the Governmental Defendants, other than those who are Voluntarily Bound Parties, the Private Defendants, and the Additional Plaintiffs that have been bound by the

[4] The following members of the Multi-State Governmental Entities Group are not Consenting Parties and are instead bound to the terms of this Order until April 21, 2021: (1) Bryant C. Dunaway, in his official capacity as the District Attorney General for the Thirteenth Judicial District, Tennessee; (2) Jennings H. Jones, in his official capacity as the District Attorney General for the Sixteenth Judicial District, Tennessee; (3) Robert J. Carter, in his official capacity as the District Attorney General for the Seventeenth Judicial District, Tennessee; (4) Brent A. Cooper, in his official capacity as the District Attorney General for the Twenty-Second Judicial District, Tennessee; and (5) Lisa S. Zavogiannis, in her official capacity as the District Attorney General for the Thirty-First Judicial District, Tennessee.

Third, Fourth, Fifth, Sixth, and Seventh, Eighth, Ninth, Tenth, Eleventh, Twelfth, Thirteenth, Fourteenth, Fifteenth, and Sixteenth Amended Orders are prohibited and enjoined from (i) the commencement or continuation of their active judicial, administrative, or other actions or proceedings against the Debtors and/or Related Parties that were or could have been commenced before the commencement of the case under this title against the Debtors and/or the Related Parties arising from or in any way relating to the Debtors' prescription opioid business, including the actions reflected in Appendix II and Appendix III, as well as (ii) from commencing or continuing any other actions against the Debtors or Related Parties alleging substantially similar facts or causes of action as those alleged in actions reflected in Appendix II and Appendix III, in each case through and including Thursday, May 20, 2021. The preliminary injunction period may be extended by further order of the Court.

ORDERED, that the April 7, 2021 Motion constitutes a joint motion of the Debtors and UCC to extend the stay beyond the Initial Stay Period as provided in paragraph 2 of the Amended and Restated Case Stipulation Among the Debtors, the Official Committee of Unsecured Creditors and Certain Related Parties, *In re: Purdue Pharma, L.P. et al.*, Case No. 19:23649 (RDD) (Nov. 20, 2019) [ECF No. 518] ("**UCC Stipulation**"). All obligations under the UCC Stipulation, inclusive of obligations of any Covered Party as defined therein, that remain in effect during the Stay Period, as defined therein, shall remain in full force and effect so long as the Preliminary Injunction, as amended and extended, remains in effect. For the avoidance of doubt, the Initial Stay Period as defined in the UCC Stipulation expired on April 8, 2020.

ORDERED, that the Debtors in these chapter 11 cases continue to be subject to the Voluntary Injunction annexed hereto as Appendix I through and including May 20, 2021.

ORDERED, that the Debtors need not give security in connection with this injunctive relief.

ORDERED, that this Order shall be promptly filed in the Clerk's Office and entered into the record.

ORDERED, that the Debtors are authorized to take all steps necessary or appropriate to carry out this Order.

ORDERED, that nothing in this Order shall prevent the Debtors from seeking a further extension of the requested injunction.

ORDERED, that if, while the preliminary injunction provided for in this Order is effective, either (i) any inactive litigation currently pending against the Debtors or Related Parties becomes active, or (ii) any new action is commenced against the Debtors or Related Parties (in either case, an "**Additional Action**"), the Debtors may promptly serve the plaintiff or plaintiffs in such Additional Action ("**Applicable Plaintiff**") with a copy of the Complaint, the Motions, the Debtors' memoranda of law in support of the Motions, and this Order (the "**Service Documents**"). The Debtors shall file a notice of such service on the docket promptly after service. If the Applicable Plaintiff in such Additional Action does not file and serve an objection within seven (7) days of service of the Service Documents, the Court may determine whether such Additional Action should be enjoined pursuant to this Order without further proceedings. If the Applicable Plaintiff files and serves an objection, the Debtors shall have the right to file and serve a response to the objection within seven (7) days of service of the objection, after which the Court may determine whether such Additional Action should be enjoined pursuant to this Order without further proceedings, or either party may seek to schedule and provide notice of a hearing.

ORDERED, that all applicable statutes of limitations and similar time limits on the commencement of Additional Actions, and all deadlines (including deadlines for appeals) in any currently pending Governmental Action, Related Party Claim or action brought by an Additional Plaintiff (including as agreed on the record at the October 11, 2019 Hearing by the representatives of the Sackler Families), shall be tolled or otherwise inoperative for the duration of this preliminary injunction. This is without prejudice to any party's rights to assert that any currently pending Governmental Action, Related Party Claim or claim brought by an Additional Plaintiff is time barred, or that commencement of any Additional Action, or any other action taken by a party with respect to any Governmental Action, Related Party Claim or Additional Plaintiff after the entry of this Order would have been time barred or untimely had it been commenced or taken before the entry of this Order.

ORDERED, that nothing in this Order shall affect or abrogate the automatic stay as to the Debtors under section 362 of the Bankruptcy Code.

ORDERED, that the time for all defendants to answer the Complaint is extended to June 10, 2021, subject to further extension by agreement of the parties and/or order of the Court. All claims and defenses of the parties, including those under Rule 12 of the Federal Rules of Civil Procedure made applicable to this proceeding by Rule 7012 of the Bankruptcy Rules, are expressly preserved.

ORDERED, that the Pre-Trial Conference in this adversary proceeding has been adjourned to June 10, 2021 at 10:00 am (Prevailing Eastern Time) before the Honorable Robert D. Drain, United States Bankruptcy Judge, at the United States Bankruptcy Court for the Southern District of New York, 300 Quarropas St., White Plains, New York, NY 10601.

ORDERED, that this Court shall retain jurisdiction to hear and determine all matters arising from or related to the implementation, interpretation, or enforcement of this Order.

Dated: April 22, 2021
White Plains, New York

/s/Robert D. Drain
THE HONORABLE ROBERT D. DRAIN
UNITED STATES BANKRUPTCY JUDGE

Appendix I

Voluntary Injunction

I. DEFINITIONS

A. "Bankruptcy Court" or "Court" shall mean the court presiding over the chapter 11 proceedings *In re Purdue Pharma L.P. et al.*, Case No. 19-23649-RDD (S.D.N.Y.).

B. "Cancer-Related Pain Care" shall mean care that provides relief from pain caused by active cancer or ongoing cancer treatment, as distinguished from treatment provided during remission.

C. "CDC Guideline Recommendations" shall mean the 12 enumerated Recommendations published by the U.S. Centers for Disease Control and Prevention (CDC) for the prescribing of opioid pain medication for patients 18 and older in primary care settings as part of its 2016 Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines), as updated or amended by the CDC.

D. "Company" shall mean the Debtors as defined in these chapter 11 proceedings *In re Purdue Pharma L.P. et al.*, Case No. 19-23649-RDD (S.D.N.Y.).

E. "Direct Customer Data" shall mean transaction information that the Company collects relating to the Company's direct customers' orders, including direct customer's wholesale orders, order history, and customer files.

F. "Downstream Customer Data" shall mean transaction information that the Company collects relating to the Company's direct customers' sales to downstream customers, including chargeback data tied to the Company providing certain discounts, "867 data," and IQVIA data.

G. "End-of-Life Care" shall mean care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.

H. "Health Care Provider" shall mean any U.S.-based physician, nurse practitioner, physician assistant, dentist, pharmacist, podiatrist, nurse, or other person engaged in the business of providing health care services and/or prescribing an Opioid Product and any medical facility, practice, hospital, clinic, or pharmacy engaged in providing health care services and/or prescribing an Opioid Product in the United States.

I. "Including but not limited to," when followed by a list or examples, shall mean that list or examples are illustrative instances only and shall not be read to be restrictive.

J. "In-Kind Support" shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.

K. "Initial Covered Sackler Persons" shall mean the Estate of Beverly Sackler, David A. Sackler, Ilene Sackler, the Estate of Jonathan D. Sackler, Jonathan D. Sackler, Kathe Sackler, Mortimer D.A. Sackler, Richard S. Sackler, Theresa Sackler, any trusts of which any of the foregoing are beneficiaries, and the trustees thereof (solely in their capacities as such), each Shareholder Party and each other entity or person that directly or indirectly

owns equity in, or has voting control over, any of the Debtors, and in the event of the death of an Initial Covered Sackler Person who is a natural person, other than a natural person who is an Initial Covered Sackler Person solely in the capacity as a trustee, the estate of such person.

L. "Lobby" and "Lobbying" shall have the same meaning as such terms have under U.S. federal law and the law governing the person or entity being lobbied.

M. "Opioid(s)" shall mean all natural, semi-synthetic, or synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain. The term "Opioids" shall not mean (i) methadone, buprenorphine, buprenorphine/naloxone (oral/sublingual), suboxone, and other substances when used exclusively to treat opioid or other substance use disorders, abuse, addiction, or overdose; (ii) raw materials and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials and/or immediate precursors are sold or marketed exclusively to DEA-licensed manufacturers or DEA-licensed researchers; or (iii) Opioids listed by the DEA as Schedule IV drugs pursuant to the federal Controlled Substances Act.

N. "Opioid Product(s)" shall mean all natural, semi-synthetic, or synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain, and that are approved by the U.S. Food & Drug Administration (FDA) and listed by the DEA as Schedule II or III drugs pursuant to the federal Controlled Substances Act (including but not limited to codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodone, oxymorphone, tapentadol, tramadol, and buprenorphine for the treatment of pain). The term "Opioid Products(s)" shall not mean (i) methadone, buprenorphine, buprenorphine/naloxone (oral/sublingual), suboxone, and other substances to treat opioid or other substance use disorders, abuse, addiction, or overdose; (ii) raw materials and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials and/or immediate precursors are sold or marketed exclusively to DEA-licensed manufacturers or DEA-licensed researchers; or (iii) Opioid Products listed by the DEA as Schedule IV drugs pursuant to the federal Controlled Substances Act.

O. "Promote," "Promoting," and "Promotion" shall mean the dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses, and/or strengths of Opioid Products.

P. "Section" shall mean, unless the context requires otherwise, a Section of this injunction.

Q. "Suspicious Order" shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder and analogous state laws and regulations.

R. "Third Party" shall mean any person or entity other than the Company or a government entity.

S. "Treatment of Pain" shall mean the provision of therapeutic modalities to alleviate or reduce pain.

T. "Unbranded Information" shall mean any information regarding an Opioid or Opioid Product that does not identify a specific product(s).

II. INJUNCTIVE RELIEF

A. Ban on Promotion

1. The Company shall not Promote Opioids or Opioid Products, including by:

   a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers or patients;

   b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products;

   c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs;

   d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network and/or social or other media account for the Promotion of Opioids or Opioid Products;

   e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides;

   f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements;

   g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products by improving rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet; and

   h. Engaging in Internet marketing techniques that Promote Opioids or Opioid Products by identifying or generating sales leads, including through pop up ads or information obtained from web forms completed by prospective patients or consumers.

2. Notwithstanding Sections II.A.1 and II.C, the Company may:

   a. Maintain corporate websites;

b. Maintain a website for any Opioid Product that contains principally the following content: the FDA-approved package insert, dosage strengths, dosage forms, packaging configurations, and medication guides; a statement directing patients or caregivers to speak with a licensed Health Care Provider; Risk Evaluation and Mitigation Strategy (REMS) materials; contact information to report an adverse event or product complaint; and/or information regarding savings programs, savings cards, vouchers, coupons, or rebate programs for the Company's Opioid Products;

c. Provide information or support the provision of information, as expressly required by (i) law, (ii) settlement agreement, (iii) court order, including order of the Bankruptcy Court, or (iv) any state or federal government agency, including providing all information necessary in order for the Company to comply with its regulatory obligations pursuant to the Federal Food, Drug, and Cosmetic Act, and/or (v) provide information about legal proceedings involving the Company;

d. Engage Health Care Providers or other Third Parties to assist the Company in responding to, preparing for, and participating in, any initiatives, advisory committees, working groups, action plans, boards, meetings and/or hearings by any state or federal government or state or federal agencies or regulators, including the Food and Drug Administration;

e. Provide the following by mail, electronic mail, on or though the Company's corporate or product websites or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products, Risk Evaluation and Mitigation Strategy materials, or other prescribing information or guidelines for Opioid Products that are published by a state or federal government agency with jurisdiction;

f. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider concerning Opioid Products by providing truthful, balanced, non-misleading, non-promotional scientific or medical information that is responsive to the specific request. Such responses should be handled by medical or scientific personnel at the Company who are independent from the sales or marketing departments;

g. Provide a response to any unsolicited question or request from a patient or caregiver by (i) directing the patient or caregiver to the FDA-approved labeling and reviewing the prescribing information with the patient as relevant to their inquiry, and, to the extent the question cannot be answered solely by reference to a specific provision of the FDA-approved labeling, providing a response that is truthful, balanced, non-misleading and fully consistent with the FDA-approved labeling, if applicable;

(ii) recommending that the patient or caregiver speak with a licensed Health Care Provider without naming any specific provider or healthcare institution; (iii) directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product; and/or (iv) directing the patient or caregiver to information concerning savings programs, vouchers, coupons, or rebate programs for the Company's Opioid Products;

h. Provide information to a payor, formulary committee, distributor, or other similar entity with knowledge and expertise in the area of health care economics concerning the cost or availability of a Company Opioid Product, including the costs compared to the cost of an Opioid Product manufactured or distributed by another company. Such information may include information about the stocking of the Opioid Product; product attributes of the Opioid Product as described in the FDA-approved labeling; tier status; applicable prescribing guidelines that are consistent with the FDA-approved labeling; step-edits for Opioid Products; restrictions; and/or prior authorization status concerning an Opioid Product;

i. Sponsor or provide financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved Risk Evaluation and Mitigation Strategy program, other federal or state law or regulation, or settlement, through an independent Third Party, which shall be responsible for determining the program's content without the participation of the Company;

j. Provide Unbranded Information in connection with managing pain in End-of-Life Care and/or Cancer-Related Pain Care relating to the use of Opioids for the Treatment of Pain, as long as the Unbranded Information identifies Company as the source of the information; and

k. Provide information about, discuss, or comment on, issues regarding mechanisms for preventing opioid abuse and misuse, including (i) abuse deterrent formulations and the use of blister packaging for opioid medications; (ii) the prevention, education, and treatment of opioid use disorders or opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose.

3. The Company shall not engage in the following specific Promotional activity relating to any products that are indicated for the treatment of Opioid-induced side effects. For the avoidance of doubt, nothing in this Section prohibits the Company's provision or dissemination of information or activities relating to: (i) the treatment of opioid use disorders; (ii) the prevention, education, and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose:

a. Employing or contracting with sales representatives or other persons to Promote products that are indicated for the treatment of Opioid-induced side effects to Health Care Providers or patients;

b. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products that are indicated for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; and

c. Engaging in any other Promotion of products that are indicated for the treatment of Opioid-induced side effects in a manner that encourages the utilization of Opioids or Opioid Products or normalizes the use of Opioids or Opioid Products for chronic pain.

4. Notwithstanding Section II.A.3 directly above, the Company may engage in other marketing activities for products that are indicated or used for the treatment of Opioid-induced side effects, so long as such activities do not Promote Opioids or Opioid Products. For the avoidance of doubt, nothing in Sections II.A.3 or 4 shall limit or otherwise restrict the ability of the Company to Promote products for occasional constipation or restrict the Company from Promoting (i) products relating to the treatment of opioid use disorders; (ii) products relating to the treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose.

5. Treatment of Pain

a. The Company shall not engage in Promotion of the Treatment of Pain in a manner that encourages the use of Opioids or Opioid Products.

b. The Company shall not Promote the concept that pain is undertreated in a manner that encourages the use of Opioids or Opioid Products.

c. The Company shall not knowingly use Third Parties to engage in the Promotion of the Treatment of Pain or Promote the concept that pain is undertreated in manners that encourage the use of Opioids or Opioid Products.

6. To the extent that the Company engages in conduct permitted by Section II.A.2 above, the Company shall do so in a manner that is:

a. Consistent with the CDC Guidelines Recommendations, as applicable; and

b. Truthful, not misleading, accurate, and not deceptive.

7. For the avoidance of doubt, nothing in this injunction shall be construed or used to prohibit the Company in any way whatsoever from taking legal or factual positions in litigation, the bankruptcy proceedings, investigations, regulatory actions and initiatives, or other legal or administrative proceedings, or exercising its right to legally challenge the enactment of any federal, state, or local legislation, rule, or regulation, or in any way whatsoever prohibit or limit the Company's right to make public statements or respond to media reports or inquires relating to any legal, administrative, regulatory, or legislative proceedings.

B. No Financial Reward or Discipline Based on Volume of Opioid Sales

1. The Company shall not provide financial incentives to its sales and marketing employees, or take disciplinary actions against its sales and marketing employees, that are directly based on, or tied to, sales volume or sales quotas for Opioid Products, unless otherwise permitted by the Bankruptcy Court.

2. The Company shall not offer or pay any remuneration directly or through a Third Party, to or from any person in return for the prescribing, sale, use or distribution of Opioid Product. For the avoidance of doubt, this shall not prohibit the provision of rebates and/or chargebacks.

C. Ban on Funding/Grants to Third Parties to Promote Opioids

1. The Company shall not provide financial support or In-Kind Support to any Third Party for purposes of Promoting Opioids or Opioid Products. For avoidance of doubt, nothing in this Section prevents the Company from directly or indirectly supporting Third Parties as required by any Judgment, court order, including order of the Bankruptcy Court, settlement, or federal or state law or regulation.

2. The Company shall not operate, control, create, sponsor, or provide financial support or In-Kind Support to any medical society or patient advocacy group for the purpose of Promoting Opioids or Opioid Products. For avoidance of doubt, nothing in this Section prevents the Company from supporting any medical society or patient advocacy group as required by any Judgment, court order, including order of the Bankruptcy Court, settlement, or federal or state law or regulation.

3. For the purposes of Promoting Opioids or Opioid Products, the Company shall not provide links to any Third Party website or materials or otherwise distribute materials created by a Third Party relating to any Opioids or Opioid Products. For avoidance of doubt, nothing in this Section prevents the Company from providing links to any Third Party website or materials or otherwise distributing materials created by a Third Parties that the Company supports as required by any Judgment, court order, including order of the Bankruptcy Court, settlement, or federal or state law or regulation.

4. The Company shall not knowingly use a Third Party, including Health Care Providers, to engage in any activity that the Company itself would be prohibited from engaging in pursuant to the injunction.

5. No director, officer, or management-level employee of the Company may concurrently serve as a director, board member, employee, agent, or officer of any entity that engages in Promotion relating to Opioids, Opioid Products, the Opioid-related Treatment of Pain, or products indicated to treat Opioid-related side effects.

6. The Company shall not advocate for the appointment of persons to the board, or hiring persons to the staff, of any entity that principally engages in the Promotion of Opioids and Opioid Products. For avoidance of doubt, nothing in this paragraph shall prohibit the Company from fully and accurately responding to unsolicited requests or inquiries about a person's fitness to serve as an employee or Board member at any such entity.

7. For the avoidance of doubt, nothing in Section II.C or this injunction shall be construed or used to prohibit the Company from providing financial or In-Kind Support to, or disseminating information about, Third Parties, including medical societies and patient advocate groups, who are principally involved in issues relating to (i) the treatment of opioid use disorders; (ii) the prevention, education, and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose.

D. Lobbying Restrictions

1. The Company shall not directly, or by employing or controlling a Third Party, Lobby for the enactment of any federal, state, or local legislation or promulgation of any rule or regulation that:

   a. Encourages or requires Health Care Providers to prescribe Opioids or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids;

   b. Would have the effect of limiting access to any non-Opioid alternative pain treatments; or

   c. Pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.

2. The Company shall not directly, or by employing or controlling a Third Party, Lobby against the enactment of any federal, state or local legislation or promulgation of any rule or regulation that supports:

a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid therapy, including but not limited to Third Party payment or reimbursement for such therapies;

b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid therapy is initiated, including but not limited to Third Party reimbursement or payment for such prescriptions;

c. The prescribing of the lowest effective dose of an Opioid, including but not limited to Third Party reimbursement or payment for such prescription;

d. The limitation of initial prescriptions of Opioids to treat acute pain;

e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to Third Party reimbursement or payment for naloxone;

f. The use of urine testing before starting Opioid therapy and annual urine testing when Opioids are prescribed, including but not limited to Third Party reimbursement or payment for such testing;

g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for Opioid Use Disorder, including but not limited to Third Party reimbursement or payment for such treatment; or

h. The implementation or use of Opioid drug disposal systems that have proven efficacy for the Company's Opioid Products.

3. The Company shall not directly, or by employing or controlling a Third Party, Lobby against the enactment of any federal, state, or local legislation or promulgation of any rule or regulation limiting the operation or use of PDMPs, including, but not limited to, provisions requiring Health Care Providers to review PDMPs when Opioid therapy is initiated and with every prescription thereafter.

4. Nothing in Section II.D or this Injunction, however, limits the Company from:

a. Challenging the enforcement of, or suing to stop the enactment of, or for declaratory or injunctive relief with respect to any legislation, rules, or regulations, including legislation, rules, or regulations relating to any issues referred to in Section II.D.1;

b. Communications made by the Company in response to a statute, rule, regulation, or order requiring such communication;

c. Communications by a representative of the Company appearing before a federal or state legislative or administrative body, committee, or subcommittee, as result of a mandatory order, subpoena commanding that person to testify, or an unsolicited request from an elected or appointed official, federal or state legislative or administrative body, committee, or subcommittee;

d. Responding to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation;

e. Communications by the Company, including to elected or appointed officials, federal or state legislative or administrative bodies, committees, or subcommittees regarding (i) mechanisms for preventing opioid abuse and misuse, including abuse deterrent formulations and the use of blister packaging for opioid medications, (ii) the prevention, education, and treatment of opioid use disorders or opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose.

5. The Company shall require all of its officers, employees, and representatives engaged in Lobbying to certify in writing to them that they are aware of and will fully comply with the provisions of this injunction with respect to Lobbying.

E. Ban on High-Dose Opioids

1. The Company shall abide by any decision by the FDA on the pending Citizens Petition dated September 1, 2017 (docket number FDA-2017-P-5396) requesting a ban on specific high doses of prescription oral and transmucosal Opioids that, when taken as directed, exceed 90 morphine milligram equivalents per day.

F. Ban on Prescription Savings Programs

1. The Company shall not directly, or by employing or controlling a Third Party, Promote savings card, vouchers, coupons, or rebate programs to Health Care Providers for any Opioid Product. Nothing in this provision shall prohibit the Company from providing savings cards, vouchers, coupons, or rebate programs, including electronic point-of-dispense programs: (i) in response to requests from Health Care Providers, patients, or other caregivers or (ii) on its website or product-specific websites.

2. The Company shall not directly or through a Third Party provide financial support to any Third Party to avoid the prohibited conduct in Section II.F.1 above.

G. Self-Monitoring and Reporting of Direct and Downstream Customers

1. The Company shall operate an effective monitoring and reporting system that shall include processes and procedures that:

a. Reasonably analyze all collected Direct Customer Data to identify a Suspicious Order of a Company Opioid Product by a direct customer;

b. Reasonably utilize available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of a Company Opioid Product;

c. Analyze all information that the Company receives that indicates an unreasonable risk of diversion activity of a Company Opioid Product or an unreasonable potential for diversion activity of a Company Opioid Product, by a direct customer or a downstream customer, including reports by employees and customers of the Company, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media; and

d. Unless otherwise required by law, upon a relevant state's request, report to the relevant state agency any direct customer or downstream customer in each state that the Company has identified as part of the monitoring required by (a)-(c), above, and any Company customer relationship in each state that was terminated by the Company because of an unreasonable risk of diversion or unreasonable risk for potential for diversion.

2. Upon request, the Company shall promptly provide reasonable assistance to law enforcement investigations of potential diversion and/or suspicious circumstances involving the Company's Opioid Products subject to, and without waiving, any applicable privilege objections.

3. If one or more of the nation's three largest pharmaceutical distributors establishes a system to aggregate data concerning transactions of Opioid Products and/or concerning reports of Suspicious Orders of Opioid Products, and the system is designed to use information provided by manufacturers of Opioid Products, the Company shall provide information to such system to the extent reasonably available and feasible, subject to, and without waiving, any applicable privilege objections.

4. The Company agrees that it will refrain from acting as a distributor of Opioid Products by providing an Opioid Product directly to a retail pharmacy or Health Care Provider or otherwise engaging in activity that requires it to be registered as a distributor under the Controlled Substances Act unless otherwise required by local, state, or federal law. Nothing in this provision, however, prevents the Company from acting as a distributor of medications relating to (i) the treatment of opioid use disorders; (ii) the treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and (iii) rescue medications for opioid overdose.

H. Appointment and Responsibilities of Monitor

1. The Company shall retain a Monitor. On February 21, 2020, the Debtors retained Thomas J. Vilsack to serve as Monitor. On February 3, 2021, Monitor Vilsack requested that he be discharged from further duties and responsibilities. On February 18, 2021, the Debtors retained Stephen Bullock, former Montana Governor and former Montana Attorney General, to replace Secretary Vilsack as Monitor.

2. The Monitor shall perform its duties according to the terms of this injunction and shall be vested with all rights and powers reasonably necessary to carry out such powers, duties, authority, and responsibilities enumerated herein.

3. The Monitor shall work with all diligence to confirm and oversee compliance with this injunction, and shall provide reports to the Company's Board of Directors and the Bankruptcy Court as outlined below.

4. The Monitor shall:

   a. subject to any legally recognized privilege and as necessary or to perform their duties hereunder, have full and complete access to the Company's personnel, books, records, and facilities, and to any other relevant information, as the Monitor may request. The Company shall develop such information as the Monitor may request and shall fully, completely and promptly cooperate with the Monitor. The Monitor may raise with the Court any issues relating to any failure of or delay in such cooperation for an expedited resolution by the Court;

   b. serve, without bond or other security, at the cost and expense of the Company, with the Monitor's fees subject to final approval by the Court. The Monitor shall have the authority to employ, upon Court approval, at the cost and expense of the Debtors' estates, such consultants, accountants, attorneys, and other representatives and assistants as are necessary to carry out the Monitor's and responsibilities. The Monitor shall serve throughout the term of this injunction and submission of a final report;

   c. have no obligation, responsibility or liability for the operations of the Company;

   d. file a report no less than every 90 days regarding compliance by the Company with the terms of this injunction; provided that elements of any such report may be filed under seal or subject to such other confidentiality restrictions contained in the Protective Order. The Court may, in response to such reports, provide further direction to the Monitor as it deems appropriate;

e. sign onto the Protective Order entered by the Court in this matter, and any confidentiality agreement consistent with the Protective Order as deemed necessary by the parties, and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants shall also sign onto the Protective Order entered by the Court, and any confidentiality agreement consistent with the Protective Order as deemed necessary by the parties; *provided, however*, that nothing shall restrict the Monitor from providing any information to the Court and the parties consistent with the terms of the Protective Order; and

f. promptly seek an order requiring compliance or such other remedies as may be appropriate under the circumstances should the Company not comply with this injunction.

5. **Disputes Regarding Compliance**

a. If an Attorney General should have a reasonable basis to believe the Company is not in compliance with the terms of this injunction, the Attorney General shall notify the Company, via the Company's General Counsel, in writing of the specific objection, including identifying the provisions of this injunction that the practice appears to violate, and give the Company thirty (30) days to respond to the notification and cure the conduct at issue, if necessary.

b. The Attorney General shall provide notification to the Monitor at the same time as notification is provided to the Company. To the extent that the Company fails to cure the alleged conduct within the thirty (30) day period, the Monitor shall have ten (10) days to determine the appropriate action and response. After that ten (10) day period and unless otherwise ordered by the Monitor or Bankruptcy Court, any Attorney General may petition the Bankruptcy Court to enforce the terms of this injunction and/or to obtain any remedy as a result of alleged non-compliance with the Company.

I. Initial Covered Sackler Persons

a. The Initial Covered Sackler Persons shall not actively engage in the opioid business in the United States (other than by virtue of their ownership of beneficial interests in the Company), and shall not take any action that would interfere with the Company's compliance with its obligations under this injunction.